20th May 2021

Letter of Correspondence regarding Project 12090: Tocotrienol-rich Vitamin E from Palm oil (Tocovid) and its effects in Diabetes and Diabetic nephropathy

Dear Sir/Madam,

As per our previous communication with MUHREC dated 20th May 2020 – we received an approval for extension for the 12090 study until 12th February 2023.

For your information, we were unable to complete the sub-study low dose of 200 mg & 100 mg OD due to the constraints of the Covid-19 pandemic since March last year. Notably, the country had gone under national lockdown as part of the effort to beat Covid-19. Currently, we are in the 3rd national lockdown and have not been able to proceed with our clinical trials. However, since the availability of the Covid-19 vaccine in Malaysian shores, since April, we are slowly seeing the regional and national vaccination programs being rolled up in the different parts of the country. We are hopeful to resume work on clinical trial maybe in the 3rd or early 4th quarter this year.

In the meantime, we have obtained additional funding to expand the study to include 300 subjects for 6 months and to compare tocotrienol with alpha-tocopherol. Otherwise, our study protocol remains unchanged.

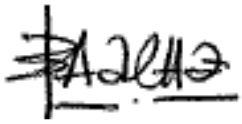
In this coming study, we will be recruiting more patients (from 90 to 300) and extending the duration of study (from 2 to 6 months). During the six months, patients will be asked to come for baseline blood tests (tocopherol levels, tocotrienol levels and growth factors) screening tests (e.g., ECG) and nerve conduction studies at our clinical sites. The nerve conduction studies will be conducted by the doctors/researchers and a trained nurse. Patients will be divided into four arms and will be given (i) Placebo once daily (ii) 100 mg Tocovid once daily (iii) 200 mg Tocovid once daily and (iv) 200IU α-tocopherol once daily respectively, for a period of 6 months and followed by a washout period of 3 months (total 9 months).

Please find attached a brief methodology section which outlines the addition/extension of the study. We will be happy to submit the full documents to the relevant section once it has been opened to us (as per FAQ no 4).

We sincerely hope the Human Ethics Committee would consider our request to increase the number of patients to 300 as well as lengthening the duration of study to 6 months, as part of Project 12090. To reiterate, we are proposing an extended study using lower dose of Vitamin E (200 mg and 100 mg once day) and alpha-tocopherol 200 IU once day for 6 months.

Many thanks for your kind consideration.

Best Regards,



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Professor Khalid Kadir

(Principal Investigator)

Dr Badariah Ahmad

(Co-Investigator)

Amendment_Summary_Lower_Dose_Study_010721

Study Title: Lower-dose Tocotrienol-rich Vitamin E (Tocovid) and its Effects in Diabetes and Diabetic Microvascular Complications: Nephropathy, Retinopathy and Neuropathy

The table below highlight some of the changes we propose to do for the coming study. **Notably, the 5 main differences are**:

(i) duration of study (from 2 to 6 months; with 3 months washout)
(ii) additional of alpha-tocopherol in the 4th arm
(iii) the sample size increase (from 90 to 300 patients)
(iv) the increase in number of visits (from 3 to 8 visits)
(v) all parameters remained the same except biomarkers will no longer be included

Apart from the differences highlighted above, the study design and protocol remained unchanged from the study.

	Old	New	Remarks – Main changes
Study duration	2 months	6 months + 3 months washout (Total 9 months)	Study duration extended to 6 months
Study drug	3 arms 1) Placebo OD (n=30) 2) 100mg Tocovid OD (n=30) 3) 200mg Tocovid OD (n=30)	4 arms 1) Placebo OD (n=75) 2) 100mg Tocovid OD (n=75) 3) 200mg Tocovid OD (n=75) 4) 200IU α-tocopherol (n=75)	Inclusion of an additional arm – 200IU α-tocopherol
Total number of subjects	90 (30 in each arm)	300 (75 in each arm)	Total number of subjects increased from 90 to 300. Randomized in 1:1:1:1 ratio, hence 75 subjects in each arm.
Visits	3 visits • Screening • Randomization • End of treatment (8 weeks)	8 visits • Screening • Randomization • Follow-up ○ 2 weeks ○ 4 weeks ○ 8 weeks ○ 12 weeks • End of treatment (24 weeks) • Washout (3 months after end of study - 36 weeks)	Additional 4 follow-up visits at 2, 4, 8 and 12 weeks after randomization. Treatment to be completed after 24 weeks. An additional wash out visit after 3 months of treatment cessation.
Parameters	• Glucose • Renal • Nerve conduction study • Fundal camera • Vitamin E	• Glucose • Renal • Nerve conduction study • Fundal camera • Vitamin E	Biomarkers are no longer measured in this study as results from previous studies showed no significant changes. The other parameters remain the same.

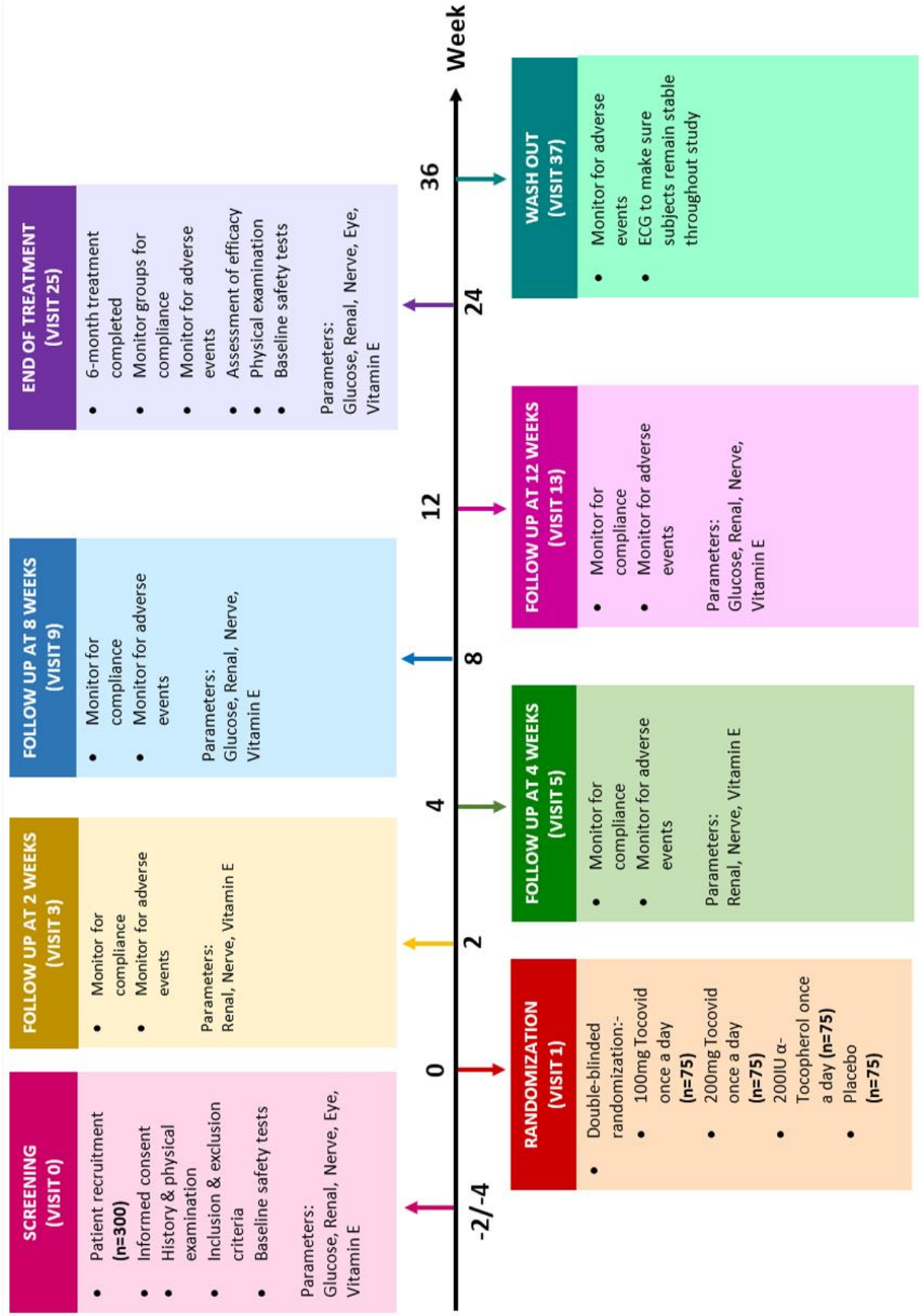

Figure 1. Study timeline

Appendix I: SAMPLE SIZE CALCULATION

Sample Size Calculation

✔ The total sample size of the study is 300 participants.

✔ Each cohort consists of 75 subjects with an allowance of maximum 10% dropout per cohort.

✔ The sample size was calculated based on the mean sural nerve conduction velocity at 8 weeks from our previous study published by Ng et al. The mean sural nerve conduction velocity for the Tocovid SupraBio® group is 45.32 ± 5.30 m/s and 42.29 ± 4.51 m/s for placebo after 8 weeks of treatment.

✔ A minimum sample size of 256 subjects, 64 in each arm, is sufficient to detect a clinically important difference of 3.03 m/s between groups in improving sural sensory nerve conduction velocity assuming a standard deviation of 5.30 using a one-way ANOVA with pairwise comparisons to achieve 80% power and a 5% level of significance. Taking into account, a maximum dropout of 10% and unforeseeable factors, a total sample size of 300 subjects for 4 treatment arms is required.

Appendix II: Explanatory Statement (English)

EXPLANATORY STATEMENT

(Relevant Participant Group)

Project: The Effect of Lower-dose Tocotrienol-rich Vitamin E (Tocovid SupraBio®) and Alpha-Tocopherol in Diabetes and Diabetic Microvascular Complications: Nephropathy, Retinopathy and Neuropathy

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You are invited to take part in this study. Please read this Explanatory Statement in full before deciding whether or not to participate in this research. If you would like further information regarding any aspect of this project, you are encouraged to contact the researchers via the phone numbers or email addresses listed above.

Amendment_Summary_Lower_Dose_Study_010721

Why were you chosen for this research?

You are invited to participate in this research study because you have type 2 diabetes mellitus with microvascular complications and we postulate that supplementary tocotrienol-rich Vitamin E from palm oil (Tocovid SupraBio®) will be able to help prevent the progression of these diabetic microvascular complications such as nephropathy (type of kidney disease), retinopathy (type of eye disease) and peripheral neuropathy (type of nerve disease).

Your contact details have been obtained from your existing records at the research centre.

What is the objective of the research?

The purpose of this study is to determine the benefits of tocotrienol-rich Vitamin E from palm oil (Tocovid SupraBio®) in patients with type 2 diabetes mellitus with early diabetic nephropathy (type of kidney disease caused by diabetes), diabetic retinopathy (type of eye disease caused by diabetes) and peripheral neuropathy (type of nerve disease caused by diabetes).

This research is necessary because diabetic nephropathy, retinopathy and neuropathy are common but essentially preventable complications of diabetes. If left untreated, diabetic nephropathy, retinopathy and neuropathy can lead to kidney failure, blindness and amputation respectively which will greatly affect your health and quality of life.

Currently, diabetic nephropathy is conventionally treated by encouraging a healthy lifestyle, optimizing blood pressure control if you have high blood pressure and reducing blood sugar to near-normal levels with oral anti-diabetic tablets and insulin. In addition, diabetic retinopathy is monitored annually using a retinal camera and may require treatment such as photocoagulation (laser treatment) to stop retinal bleeds. Peripheral neuropathy is assessed by the presence or absence of sensation in your lower limbs (i.e. numbness, pain, ulcers etc) and is also treated by improving blood glucose and supplements (i.e. Vitamin B12). However, all these treatments may not be enough to prevent the progression of diabetic nephropathy, retinopathy and neuropathy. Therefore, addition of Tocotrienol-rich Vitamin E acts as a potent antioxidant to reduce certain harmful compounds which we believe are important causes of diabetic nephropathy, retinopathy and neuropathy.

Tocotrienol-rich Vitamin E has shown a great promise in our previous studies as an antioxidant capable of preventing the development and progression of diabetic-related complications. Results from our pilot phase study in 2018 showed that supplementation of 200mg Tocovid SupraBio® twice a day at two and three months significantly reduced serum creatinine and

increased eGFR[1,2]. This finding was verified in our phase IIb study where 12-month of 200mg twice a day Tocovid supplementation improved kidney function as assessed by serum creatinine and eGFR[3]. Significant reduction in retinal hemorrhage in the right eye, liver enzymes AST and ALT were also found in our pilot phase study[4]. Results from our previous phase IIb study showed there was a statistically significant improvement in the nerve conduction studies parameters after 8 weeks of 200mg Tocovid SupraBio® supplementation twice daily[5].

Hence, this study is important to identify the effect of lower dose Tocovid SupraBio® in diabetic patients with early nephropathy, retinopathy and neuropathy. An additional arm of 200IU natural alpha-tocopherol is also included as a comparator in this study to prove that the effects seen are solely due to tocotrienol in Tocovid SupraBio®.

Additional treatment from this study will not affect or change your current treatment.

Timeline of study

- Your participation will be a total of approximately 9 months.
- There will be 8 visits in total.
- All visits will take approximately 3.5 hours each except Visit 1 for randomisation will take approximately 2 hours.
- Please refer to Diagram 1 below to see an overview of the timeline of the study and parameters to be investigated in each visit.

[1] Tan SM, Chiew Y, Ahmad B, Kadir KA. Tocotrienol-rich vitamin E from palm oil (tocovid) and its effects in diabetes and diabetic nephropathy: a pilot phase II clinical trial. Nutrients. 2018 Sep;10(9):1315.

[2] Tan GC, Tan SM, Phang SC, Ng YT, Ng EY, Ahmad B, Palamisamy UD, Kadir KA. Tocotrienol-rich vitamin E improves diabetic nephropathy and persists 6–9 months after washout: a phase IIa randomized controlled trial. Therapeutic advances in endocrinology and metabolism. 2019 Dec;10:2042018819895462.

[3] Koay YY, Tan GC, Phang SC, Ho JI, Chuar PF, Ho LS, Ahmad B, Abdul Kadir K. A Phase IIb Randomized Controlled Trial Investigating the Effects of Tocotrienol-Rich Vitamin E on Diabetic Kidney Disease. Nutrients. 2021 Jan;13(1):258.

[4] Chiew Y, Tan SM, Ahmad B, Khor SE, Kadir KA. Tocotrienol-rich vitamin E from palm oil (Tocovid) and its effects in diabetes and diabetic retinopathy: a pilot phase II clinical trial. Asian Journal of Ophthalmology. 2021 Apr 16;17(4):375-99.

[5] Ng YT, Phang SCW, Tan GCJ, Ng EY, Botross Henien NP, UD MP, et al. The Effects of Tocotrienol-Rich Vitamin E (Tocovid) on Diabetic Neuropathy: A Phase II Randomized Controlled Trial. Nutrients. 2020;12(5).

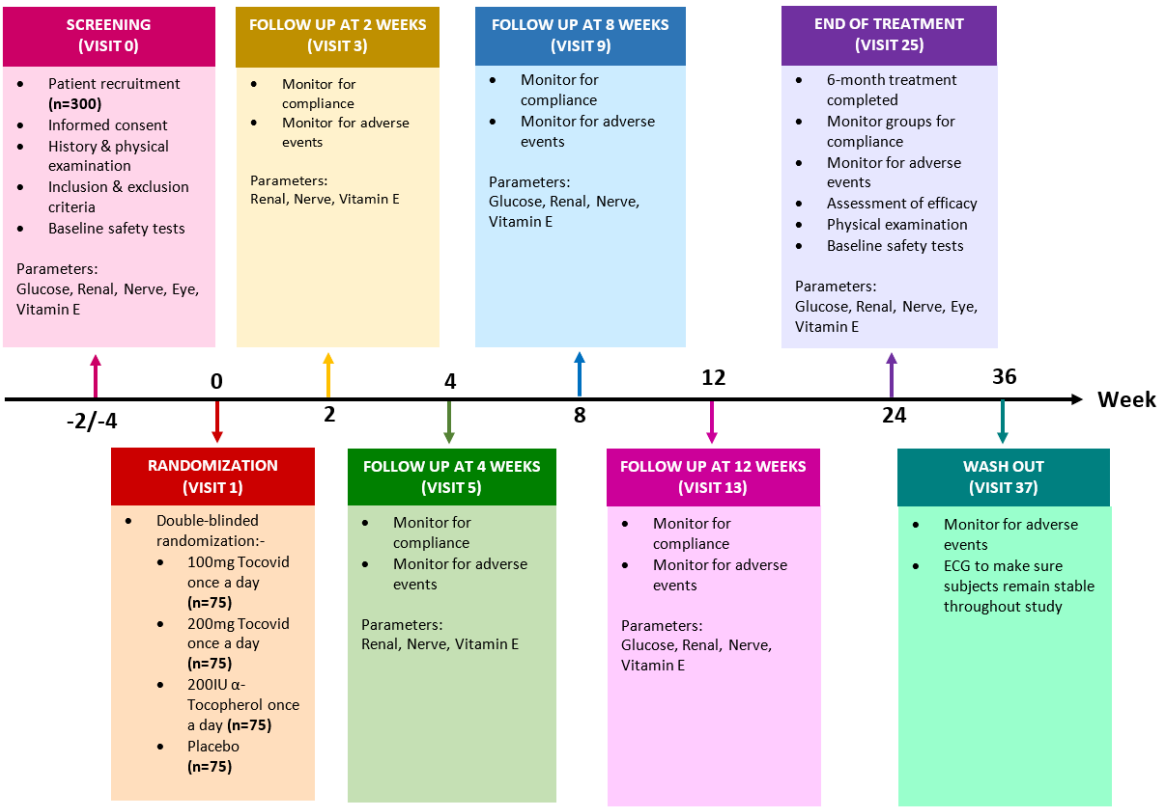

Diagram 1: Overall Study Design

A total of 25ml of blood samples (5 tubes) will be taken during screening, Visit 9, Visit 13 and End of Treatment Visit. 21ml of blood samples (3 tubes) will be obtained during Visit 3 and Visit 5 for assessment of renal function and Vitamin E levels.

A total of 20ml of urine will be taken in all visits.

An electrocardiogram (ECG) is a test which measures the electrical activity of your heart to show whether or not it is working normally. You will be asked to lie down and small electrode patches will be put on the skin of your chest, arms and legs. It is a non-invasive and painless procedure. This test will be done at Screening Visit, End of Treatment Visit and Wash Out Visit.

A nerve conduction study (NCS) is a test which measures how fast or slow the nerve activity travels down your nerves. You will be asked to lie down on a bed and small electrode patches will be put on the skin of your legs. A small current will be conducted on the nerves in your leg to measure the electrical impulse travelling in the nerves of your leg. You might feel a small amount of discomfort (i.e. a small tingling sensation) when the current is being conducted in your nerves. Two nerves will be tested on your lower limbs bilaterally, namely the sural sensory nerve and tibial motor nerve. The test will take approximately 15 to 20 minutes. This test will be done at all visits except Randomisation Visit and Wash Out Visit.

In addition, you will be asked to fill up a Neuropathic Pain Questionnaire in order for us to thoroughly understand what type of pain you are suffering so that we can assess and treat your pain problem.

A fundus camera test is a test which views the back of your eye (retina) and allows the researcher to see if there is any bleeding in the retina. The pupils of your eyes will be dilated using an eyedrop. It might take 15-20 minutes for your pupils to be fully dilated. Once you are ready, you will be called to sit in a darkened room by the researcher. The researcher will take several views in order to get the best view of the retina. The test will take approximately 15-20 minutes. This test will be done at Screening Visit and End of Treatment Visit.

During the randomisation, we will allocate you into one of the four groups: 100mg of Tocovid SupraBio® once a day, 200mg of Tocovid SupraBio® once a day, 200IU of alpha-tocopherol once a day or placebo containing cooking palm oil once a day in a ratio of 1:1:1:1. The randomisation is done manually according to your age, gender, duration of diabetes and levels of HbA1c. The drugs will be labelled as “study drug A”, “study drug B”, “study drug C” or “study drug D”. All drugs will look similar and the identity will not be known by the investigator or the patient until the end of the study.

What you should do before coming for each visit

Before coming all the visits, you are required to:

- ✔ Fast for at least 8 hours (only plain water allowed)
- ✔ Medication
    - DO NOT take morning dose of anti-diabetic medication (as you will be fasting)
    - Take usual dose antihypertensive and other medications
    - Bring study drug
    - Bring all new medications and supplements
- ✔ Bring all laboratory/diagnostic test results for review
- ✔ [Females only] Inform us if you are having your period so that we can arrange for another suitable appointment
- ✔ Inform us if you are unable to come for the appointment date so that we can arrange for another suitable appointment
- ✔ Avoid strenuous activity the night before
- ✔ Nerve conduction study
    - DO NOT wear tight pants as a stimulating electrode will be placed on the skin at the back of your knee
    - DO NOT apply lotion or cream on your lower limbs as these may prevent electrodes from sticking properly
- ✔ Fundus camera
    - DO NOT wear contact lens as your pupils will be dilated with an eye drop

Risks of withholding morning dose of anti-diabetic medication

You may experience signs and symptoms of low blood sugar such as fatigue, shakiness, sweating and dizziness if you withhold your morning dose of anti-diabetic medication. In order to address this, once your blood samples are taken, including fasting blood sugar, you will be given a complimentary Hot Beverage (hot chocolate, tea or coffee) and some biscuits. Then, you will be allowed to take the morning dose of your anti-diabetic medication.

Depending on the severity of your symptoms, you may have to consume a sugary drink or snack immediately. Subsequently, your blood glucose levels will be monitored until it is optimised. If you cannot tolerate orally, we will administer a medication through your veins. If your condition deteriorates, you will be referred to the nearest hospital for additional treatment.

Source of funding

This project is funded by the Malaysian Palm Oil Board. The study drugs are donated by *Hovid-Integrated Global Pharmaceutical Partner Berhad*.

There is no conflict(s) of interest or any competing interest(s) with the sponsor or among the study team members.

Consenting to participate in the project and withdrawing from the research

The details of the research trial are described in this document. It is important that you understand why the research is being done and what it will involve. After you are properly satisfied that you understand this study, and that you wish to participate, you must sign two informed consent forms; one is for you to keep and the other must be returned to the investigator.

Your participation in this study is voluntary. You do not have to be in this study if you do not want to. You may withdraw from it at any time. You may also refuse to answer any questions that you do not wish to answer. Your refusal to participate or withdrawal will not affect any medical or health benefits to which you are otherwise entitled.

If you withdraw from the study, any data collected from you up to your withdrawal will still be used for the study and you will be asked to attend one last follow-up visit (discontinuation visit) to ensure that you are healthy. During this visit, the investigating team will take your history, perform a physical examination and conduct several safety tests.

Participants who require counselling services will be referred directly for consultation to the chief investigator, Professor Khalid Abdul Kadir. If necessary, he will arrange for referral to counsellors or psychologists at the appropriate facilities.

Possible benefits and risks to participants

Tocotrienol is postulated to prevent the development and/or progression of complications arising from diabetes, including nephropathy, retinopathy and neuropathy. There may or may not be any benefits to you. Nevertheless, the information obtained from this study will help to improve the treatment or management of other patients with the same disease or condition.

There are no known side effects of Tocovid SupraBio® and natural alpha-tocopherol (active drugs) or the inactive drug (placebo containing cooking palm oil). According to the Drug Control Authority of Malaysia, Tocovid SupraBio® and Hovid Vitamin E 200IU is approved as a health supplement safe for consumption. Nevertheless, you will be monitored for any side effects at the end of the 6-month treatment period. If you have any concerns, you can contact the investigators either personally, by phone call or email. If a side effect occurs, the investigator may choose to withdraw you from the clinical trial based on his/her discretion. Participants who are withdrawn will be followed up with a discontinuation visit as mentioned previously. The duration of follow-up of the adverse event will be based on the investigator and study team's discretion.

The effect of the study product on an unborn child is not known. Female participants should not breastfeed her baby while in the study as the study product may be present in the breast milk. You should also avoid becoming pregnant or fathering a child while in this study. Women of childbearing age will be given a pregnancy test to confirm they are not pregnant. It is important that you use highly effective birth control methods consistently and correctly; the study doctor

will discuss these methods with you. Notify your study doctor immediately if you think that you or your partner has become pregnant during the study. If you or your partner is pregnant, the study therapy will be discontinued immediately and you will be removed from the study. However, we would like to follow your pregnancy until term to ensure the health of you and your newborn baby.

During randomization, your study subject number will be used to identify you instead of your name, therefore there is very minimal risk of disclosure of your personal information to the public. We will also inform you in a timely manner about any new findings or changes about the study product which may affect your health or willingness to continue in this study. Where necessary, you may be asked to re-consent to participate.

Research involving diagnostic testing or possible incidental findings

We will usually ask our participants if they wished to be informed of (i) any diagnostic findings, (ii) incidental findings, and/or (iii) only those adverse findings that would usually lead directly to treatment. You will also be asked whether you would like any of these findings to be discussed by your family doctor, another doctor of your choice, or by a member of the research team.

If you have consented to any of the above, the research team will inform you accordingly throughout the trial. You will however, not be informed if you are taking the active drug or inactive drug as it will affect the results of the study.

Payment

You will be reimbursed RM*30* per visit for your travel expenses to our Clinical Research Centre, even if you choose to undertake only part of the requirements or withdraw from the research early.

Confidentiality

The nature of this clinical trial requires personal information to be collected from you through history-taking, physical examination and tests. However, only information pertaining to your eligibility for recruitment will be obtained. Once recruited, you will only be identified by a study subject number that has no relation to your personal information or personal identifiers. Each subject number is unique and accessible only by investigators. The master list which contains your particulars will only be made accessible to the Chief Investigator. Data collection on data sheets and subsequent analysis will utilize only your subject number. The master list of study subjects will be destroyed once findings for this study are published.

All your information obtained in this study will be kept and handled in a confidential manner, in accordance with applicable laws and/or regulations. When publishing or presenting the study results, your identity will not be revealed without your expressed consent. Investigators of this study, qualified monitors or auditors, study sponsor or its affiliates and governmental or regulatory authorities may inspect and copy your medical records, where appropriate and necessary.

Data from the study will be archived and may be transmitted outside the country for the purpose of analysis, but your identity will not be revealed at any time.

Storage of data

Data gathered for this study will be stored in a file kept in a locked cabinet in a locked room. Upon completion of the study, all data will be stored and handled by Monash University Malaysia for a minimum of 15 years after the study has ended.

The blood serum taken from you will be used to identify biomarkers for diabetic nephropathy, retinopathy, and neuropathy. A few millilitres of your serum samples will be kept for 2 years for future testing of other biomarkers once funds are available. No genetic testing will be conducted on your biospecimen. Your biospecimen will be coded and any information that can identify you will be removed. Only your study doctor and study staff will be able to link the code with you. The sponsor may share your biospecimen with other researchers but your identity will remain confidential. You can withdraw your consent and your biospecimen will be destroyed but any information previously obtained from your biospecimen can be used for this research study.

Use of data for other purposes

Data gathered for this study will not be used for any future study without prior approval from relevant regulatory bodies and/or ethical committee(s). Please be assured that only aggregate de-identified data may be used for other projects where ethics approval has been granted.

Results

The results of the trial will be made available by the end of next year. If you wish to access your test results during the study, you may contact your study doctor or the investigating team by phone, email or at the Clinical Research Centre.

Complaints

Should you have any concerns or complaints about the conduct of the project, you are welcome to contact the Deputy Head of School (Graduate Research), Jeffrey Cheah School of Medicine and Health Sciences, Monash University Malaysia:

Professor Iekhsan Othman
Deputy Head of School (Graduate Research),
Jeffrey Cheah School of Medicine and Health Sciences
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Thank you,

Professor Dato' Dr Khalid Abdul Kadir

Chief Investigator

Jeffrey Cheah School of Medicine and Health Sciences,
Monash University Malaysia.

Appendix III: Informed Consent (English)

INFORMED CONSENT FORM (PARTICIPANT COPY)

Project: The Effect of Lower-dose Tocotrienol-rich Vitamin E (Tocovid SupraBio®) and Alpha-Tocopherol in Diabetes and Diabetic Microvascular Complications: Nephropathy, Retinopathy and Neuropathy

Chief Investigator: Professor Dato' Dr Khalid Abdul Kadir

I have been asked to take part in the Monash University research project specified above. I have read and understood the Explanatory Statement and I hereby consent to participate in this project.

I consent to the following:	Yes	No
1. The data/tissue samples that I have provided during this research will be kept for 2 years and may be used by the Investigating team to test for other identified biomolecular markers once funds are available		
2. In the event of there being an incidental finding, I would like to be advised of:		
(a) Any diagnostic findings		
(b) Any incidental findings		
(c) Only those adverse findings that would usually lead directly to treatment		
3. In the event of there being an incidental finding, I would like to be advised of any diagnostic/incidental/adverse findings to be discussed with me by my:-		
(a) Usual family doctor		
(b) Another doctor of your choice		
(c) Or by a member of the research team		

Participant:

Signature: **IC number:**

Name: **Date:**

Investigator conducting informed consent:

Signature: **IC number:**

Name: **Date:**

INFORMED CONSENT FORM (INVESTIGATOR COPY)

Project: The Effect of Lower-dose Tocotrienol-rich Vitamin E (Tocovid SupraBio®) and Alpha-Tocopherol in Diabetes and Diabetic Microvascular Complications: Nephropathy, Retinopathy and Neuropathy

Chief Investigator: Professor Dato' Dr Khalid Abdul Kadir

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3. In the event of there being an incidental finding, I would like to be advised of any diagnostic/incidental/adverse findings to be discussed with me by my:-		
(a) Usual family doctor		
(b) Another doctor of your choice		
(c) Or by a member of the research team		

Participant:

Signature: **IC number:**

Name: **Date:**

Investigator conducting informed consent:

Signature: **IC number:**

Name: **Date:**

Appendix IV: Explanatory Statement (Malay)

KENYATAAN PENYELIDIKAN

(Untuk Kumpulan Peserta Penyelidikan Yang Berkaitan)

Projek: Kesan Dosis Rendah Vitamin E yang Kaya dengan Tokotrienol daripada Minyak Kelapa Sawit (Tocovid SupraBio®) dan Alfa-Tokoferol terhadap Diabetes dan Komplikasi Mikrovaskular Diabetes: Nefropati (Buah Pinggang), Retinopati (Mata) dan Neuropati (Urat Saraf)

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Anda telah dijemput untuk menyertai penyelidikan ini. Sila ambil masa yang sepenuhnya untuk membaca penyataan penjelasan ini sebelum membuat keputusan untuk menyertai penyelidikan ini. Jika anda memerlukan maklumat yang lebih lanjut tentang penyelidikan ini,

anda digalakkan untuk menghubungi penyelidik-penyelidik di atas melalui emel atau telefon bimbit yang tertera di atas.

Mengapakah anda dipilih untuk menyertai penyelidikan ini?

Anda telah dijemput untuk menyertai penyelidikan ini kerana anda mempunyai diabetes mellitus jenis 2 dengan komplikasi tahap awal diabetes - kerosakan buah pinggang (nefropati), kerosakan mata (retinopati) dan kerosakan urat saraf (neuropati). Kami menjangkakan rawatan tambahan tokotrienol kaya dalam Vitamin E daripada minyak kelapa sawit (Tocovid SupraBio®) akan dapat membantu anda mengurangkan kerosakan buah pinggang, mata dan urat saraf akibat diabetes.

Butiran hubungan anda telah diambil daripada rekod kami.

Apakah tujuan penyelidikan ini dilakukan?

Tujuan penyelidikan ini dilakukan adalah untuk menentukan faedah-faedah Vitamin E yang kaya dengan tokotrienol daripada minyak kelapa sawit (Tocovid) kepada pesakit diabetes mellitus jenis 2 dengan nefropati diabetik awal (jenis penyakit buah pinggang akibat diabetes), retinopati diabetik (jenis penyakit mata disebabkan oleh diabetes) dan neuropati periferal (jenis penyakit saraf yang disebabkan oleh diabetes).

Penyelidikan ini amat penting dan diperlukan kerana kejadian nefropati, retinopati dan neuropati diabetik adalah sangat tinggi, walaupun sebenarnya kejadian ini boleh dicegah. Sekiranya tidak dirawat, nefropati diabetik boleh menyebabkan kegagalan buah pinggang tahap terakhir. Kerosakan mata dan urat saraf boleh menyebabkan pendaharahan kecil di belakang mata (retina) ataupun amputasi kaki. Semua komplikasi ini akan menjejaskan kesihatan dan kualiti kehidupan anda.

Biasanya, kencing manis dirawat dengan pengawalan paras gula darah dan tekanan darah tinggi melalui ubat-ubatan dan perubahan gaya hidup seperti penurunan berat badan, bersenam dan pengawalan pemakanan. Tambahan pula, nefropati diabetik dipantau setiap tahun dengan kamera retina dan rawatan seperti photocoagualtion (rawatan laser) mungkin diperlukan untuk menghentikan pendarahan retina. Neuropati periferal dinilai dengan menguji sekiranya anda berasa atau tidak berasa sensasi di anggota bawah badan anda (contohnya kebas, sakit, ulser dan lain-lain lagi). Neuropati periferal juga dirawat dengan mengawal glukosa darah dan suplemen (seperti Vitamin B12). Namun demikian, penyelidikan semasa menunjukkan bahawa rawatan utama ini tidak cukup untuk memberikan anda perlindungan yang sempurna daripada kerosakan buah pinggang, mata dan urat saraf disebabkan oleh diabetes. Oleh itu, rawatan tambahan seperti Vitamin E yang kaya dengan tokotrienol memainkan peranan yang penting sebagai antioksidan yang kuat untuk mengurangkan sebatian berbahaya yang kami percayai adalah sebab penting bagi nefropati, retinopati dan niuropati diabetik.

Dalam kajian kami yang terdahulu, Tocovid SupraBio® telah menunjukkan potensi yang cerah sebagai antioksidan yang selamat dimakan serta mampu mencegah kejadian dan

perkembangan komplikasi diabetes. Hasil dari kajian fasa rintis kami pada 2018 menunjukkan suplementasi 200mg Tocovid SupraBio® dua kali sehari selama dua dan tiga bulan menurunkan kreatinin serum dan meningkatkan Anggaran Kadar Penurasan Glomerular (eGFR)[6,7]. Penemuan ini disahkan dalam kajian fasa IIb kami di mana suplementasi 200mg Tocovid SupraBio® dua kali sehari selama 12 bulan telah memperbaiki fungsi buah pinggang secara ketara seperti yang dinilai oleh kreatinin serum dan Anggaran Kadar Penurasan Glomerular (eGFR)[8]. Pengurangan pendarahan retina di mata kanan, enzim hati AST dan ALT yang ketara juga didapati dalam kajian fasa rintis kami[9]. Hasil dari kajian fasa IIb kami sebelumnya telah menunjukkan peningkatan yang signifikan dalam parameter kajian pengaliran saraf selepas pengambilan 200mg Tocovid SupraBio® dua kali sehari selama 8 minggu[10].

Oleh itu, kajian ini adalah penting untuk mengenal pasti kesan dosis rendah Tocovid SupraBio® pada pesakit diabetes dengan nefropati tahap awal, retinopati dan neuropati. Satu kumpulan tambahan, iaitu 200IU alfa-tokoferol semula jadi juga dimasukkan dalam kajian ini sebagai pembanding untuk membuktikan kesan yang dijumpai adalah disebabkan oleh tokotrienol dalam Tocovid SupraBio® sahaja.

Rawatan tambahan ini tidak akan menjejaskan atau menyebabkan sebarang penukaran dalam rawatan anda sekarang.

Garis masa kajian

- Tempoh penyertaan anda adalah selama 9 bulan.
- Jumlah lawatan adalah 8.
- Semua lawatan akan mengambil masa kira-kira 3.5 jam kecuali Lawatan 1 yang menglibatkan pengagihan secara rawak akan mengambil masa kira-kira 2 jam.
- Sila rujuk Rajah 1 di bawah untuk gambaran keseluruhan kajian ini dan parameter yang akan diuji dalam setiap lawatan.

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[8] Koay YY, Tan GC, Phang SC, Ho JI, Chuar PF, Ho LS, Ahmad B, Abdul Kadir K. A Phase IIb Randomized Controlled Trial Investigating the Effects of Tocotrienol-Rich Vitamin E on Diabetic Kidney Disease. Nutrients. 2021 Jan;13(1):258.
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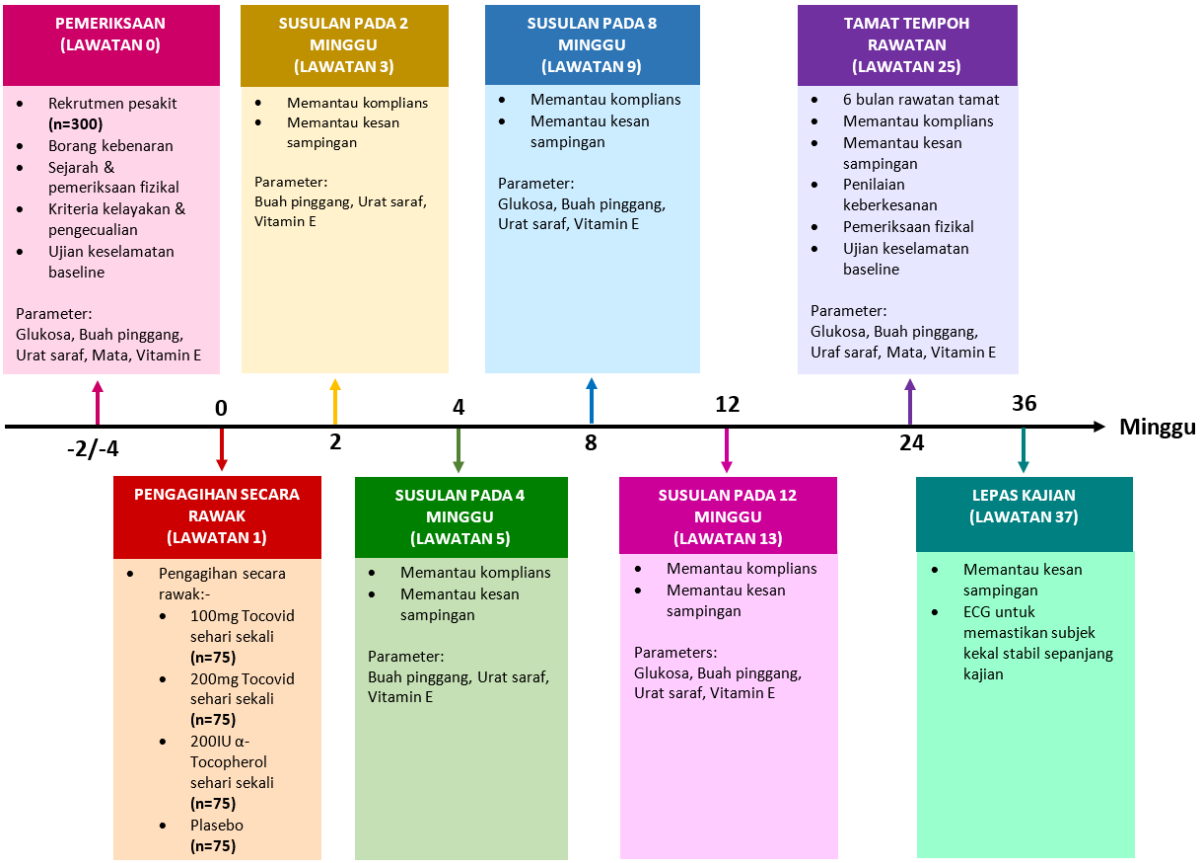
[10] Ng YT, Phang SCW, Tan GCJ, Ng EY, Botross Henien NP, UD MP, et al. The Effects of Tocotrienol-Rich Vitamin E (Tocovid) on Diabetic Neuropathy: A Phase II Randomized Controlled Trial. Nutrients. 2020;12(5).



Rajah 1: Gambaran Keseluruhan Kajian

Sebanyak 25ml darah (5 tiub) akan diambil pada masa Lawatan Screening, Lawatan 9, Lawatan 13 dan Lawatan Tamat Tempoh Rawatan. 21ml darah (3 tiub) akan diambil pada Lawatan 3 and 5 untuk penilaian fungsi buah pinggang dan tahap Vitamin E.

Sebanyak 20ml air kencing akan diambil dalam semua lawatan.

Elektrokargiogram (ECG) adalah ujian yang mengukur aktiviti elektrik jantung untuk memastikan jantung anda berfungsi seperti biasa. Anda akan diminta untuk membaring rata di atas katil pemeriksaan dan elektrod kecil akan ditampal pada kulit dada, lengan dan kaki. Ujian ini bukan invasif dan merupakan prosedur yang tidak menyakitkan. Ujian ini akan dikendalikan pada Lawatan Pemeriksaan, Lawatan Tamat Tempoh Rawatan dan Lawatan Lepas Kajian.

Kajian pengaliran saraf (NCS) boleh menentukan kelajuan impuls saraf yang melalui urat saraf di tangan dan kaki anda. Anda akan diminta untuk membaring rata di atas katil pemeriksaan dan elektrod kecil akan diletakkan pada kulit yang mengatasi saraf di bahagian kaki. Arus yang kecil akan dilakukan pada saraf di kaki untuk mengukur impuls elektrik yang bergerak di saraf kaki anda. Semasa prosedur ini dijalankan, anda mungkin rasa kurang selesa (cth. semut-semut) apabila arus elektrik melalui saraf anda. Dua urat saraf akan dikaji dalam kajian ini,

iaitu saraf sural dan saraf tibial. Kajian ini memakan masa 15-20 minit. Ujian ini akan dikendalikan pada semua lawatan kecuali Lawatan 1 dan Lawatan Lepas Kajian.

Tambahan pula, anda dikehendaki melengkapkan soal selidik kesakitan neuropatik supaya kami dapat memahami jenis kesakitan yang anda alami untuk menilai dan merawat masalah kesakitan anda.

Ujian kamera fundal adalah untuk memeriksa retina di belakang mata anda. Ujian ini membolehkan penyelidik melihat sekiranya terdapat pendarahan kecil pada retina anda. Sebelum ujian ini dimulakan, mata anda akan dititiskan dengan ubat titisan mata yang mampu membesarkan anak mata. Anda mesti menunggu selama 15-20 minit, sehingga anak mata sudah benar-benar terbuka besar. Selepas itu, anda akan dipanggil masuk ke dalam bilik gelap untuk ujian. Penyelidik akan mengambil beberapa pandangan untuk mendapatkan pandangan retina yang terbaik. Ujian ini dijangka mengambil masa selama 15 -20 minit untuk mengambil gambar retina mata anda dan akan dikendalikan pada Lawatan Screening dan Lawatan Tamat Tempoh Rawatan.

Dalam Lawatan Pengagihan Secara Rawak, anda akan dibahagi 1:1:1:1 sama ada ke kumpulan aktif (100mg Tocovid SupraBio®sekali sehari, 200mg Tocovid SupraBio® sekali sehari, 200IU alfa-tokoferol semula jadi sekali sehari) atau kumpulan kawalan (ubat tidak aktif; plasebo mengandungi minyak masak kelapa sawit). Pengasingan ini akan dibuat berdasarkan umur, jantina, tempoh diabetes dan tahap HbA1c anda. Ubat akan dilabel sebagai “ubat kajian A”, “ubat kajian B”, “ubat kajian C” atau “ubat kajian D”. Keempat-empat ubat kajian ini mempunyai rupa yang sama dan identitinya tidak akan diketahui oleh anda atau penyelidik sampai kajian ini diakhiri.

Perkara-perkara yang perlu anda buat sebelum datang untuk setiap lawatan

Sebelum datang untuk semua lawatan, anda dikehendaki: -

- ✔ Berpuasa selama sekurang-kurangnya 8 jam (hanya air kosong yang dibenarkan)
- ✔ Ubat-ubatan
  - JANGAN mengambil ubat diabetes dos pagi (kerana anda akan berpuasa)
  - Makan ubat darah tinggi dan ubat-ubatan lain yang biasanya diambil pada waktu pagi
  - Bawa ubat kajian
  - Bawa semua ubat atau suplemen baru
- ✔ Bawa semua ujian makmal/ujian diagnostik anda untuk semakan
- ✔ [Untuk wanita sahaja] Maklumkan kami jika anda mempunyai haid supaya kami dapat mengatur satu lawatan lain yang sesuai untuk anda
- ✔ Maklumkan kami jika anda tidak dapat datang supaya kami dapat mengaturkan satu lawatan lain yang sesuai untuk anda
- ✔ Elakkan aktiviti berat/intensif pada malam sebelumnya
- ✔ Kajian pengaliran saraf (NCS)
  - JANGAN memakai seluar ketat kerana elektrod akan diletakkan pada kulit di bahagian belakang lutut anda

- JANGAN sapukan losyen atau krim pada anggota bawah anda kerana ini boleh mengelakkan elektrod melekat dengan betul

✔ Kamera fundal

- JANGAN memakai kanta lekap kerana anak mata anda akan dibesarkan dengan ubat titisan mata

Risiko pertahanan dos pagi ubat anti-diabetik

Anda mungkin akan mengalami tanda-tanda gula darah rendah seperti keletihan, kelemasan, berpeluh dan pening jika anda menahan dos ubat anti-diabetes anda. Untuk menangani masalah ini, sebaik sahaja sampel darah anda diambil, termasuk gula darah puasa, anda akan diberikan minuman panas pelengkap (coklat panas, teh atau kopi) dan beberapa keping biskut. Kemudian, anda akan dibenarkan mengambil dos pagi ubat anti-diabetes anda.

Bergantung pada keparahan gula darah rendah anda, anda mungkin perlu mengambil minuman manis atau snek dengan serta-merta. Seterusnya, tahap glukosa darah anda akan dipantau sehingga ia dioptimumkan. Jika anda tidak boleh menelan, kami akan memberikan ubat melalui urat anda. Sekiranya keadaan anda merosot, anda akan dirujuk ke hospital terdekat untuk mendapatkan rawatan tambahan.

Sumber pembiayaan

Penyelidikan ini menerima tajaan daripada Lembaga Minyak Sawit Malaysia. Ubat-ubat kajian disumbang oleh *Hovid-Integrated Global Pharmaceutical Partner Berhad*.

Tiada potensi konflik kepentingan atau apa-apa kepentingan bersaingan dengan pihak penaja serta di antara ahli pasukan kajian kami.

Pemberian kebenaran untuk menyertai kajian dan penarikan diri daripada penyelidikan

Pernyataan ini menjelaskan hal-hal berkenaan penyelidikan kami dengan lebih mendalam dan terperinci. Ianya amat penting anda memahami sebab-sebab penyelidikan ini dijalankan dan apa yang perlu dilakukan dalam penyelidikan ini. Setelah anda berpuas hati bahawa anda memahami penyelidikan ini dan berminat untuk turut serta, anda dikehendaki menandatangani dua Borang Kebenaran Peserta. Satu borang akan disimpan oleh anda dan borang yang kedua patut dikembalikan kepada penyelidik.

Penyertaan anda dalam penyelidikan ini adalah secara sukarela. Anda tidak perlu menyertai penyelidikan ini jika anda tidak mahu. Anda boleh menarik diri daripada penyelidikan ini pada bila-bila masa. Anda juga mempunyai hak untuk tidak menjawab mana-mana soalan yang dikemukakan. Jika anda tidak mahu menyertai ataupun menarik diri dari penyelidikan ini, tindakan anda tidak akan menjejaskan segala hak dan keistimewaan perkhidmatan perubatan dan kesihatan yang selayaknya anda terima.

Jika anda menarik diri, segala maklumat yang telah diperolehi sebelum anda menarik diri tetap akan digunakan dalam penyelidikan ini dan anda akan dijemput untuk menghadiri

lawatan susulan yang terakhir (lawatan pemberhentian) untuk memastikan anda sihat. Dalam lawatan terakhir ini, kami akan mengadakan temuduga yang teliti, pemeriksaan tubuh badan yang lengkap serta beberapa ujian keselamatan.

Peserta yang memerlukan perkhidmatan kaunseling akan dirujuk secara langsung untuk berunding dengan ketua penyiasat, Profesor Khalid Abdul Kadir. Sekiranya perlu, beliau akan mengatur rujukan kepada kaunselor atau ahli psikologi di kemudahan yang sesuai.

Faedah-faedah dan kemungkinan risiko terhadap peserta

Tokotrienol dirumuskan untuk mencegah perkembangan komplikasi yang timbul daripada diabetes, termasuk nefropati, retinopati dan neuropati diabetik. Setakat ini, kami tidak boleh mengetahui sekiranya anda boleh mendapat manfaat daripada kajian ini ataupun tidak. Namun demikian, maklumat yang diperolehi daripada kajian ini akan membantu meningkatkan kualiti rawatan atau pengurusan pesakit lain yang menpunyai penyakit yang serupa dengan anda.

Walau bagaimanapun, setakat ini belum ada kesan sampingan yang diketahui daripada Tocovid (rawatan aktif) atau plasebo (rawatan inaktif). Menurut Pihak Berkuasa Kawalan Dadah Malaysia, Tocovid diluluskan sebagai suplemen kesihatan yang selamat untuk dimakan. Walau bagaimanapun, kami akan memantau sebarang kesan sampingan semasa lawatan tamat tempoh rawatan selama 8 minggu. Jika anda mempunyai sebarang kebimbangan, anda boleh menghubungi kami, sama ada secara peribadi, melalui panggilan telefon atau e-mel. Sekiranya berlaku kesan sampingan, penyiasat boleh memilih untuk mengeluarkan anda dari kajian berdasarkan budi bicaranya. Jika anda tidak lagi terlibat dalam kajian ini, anda akan dijemput untuk datang ke lawatan pemberhentian seperti yang dinyatakan sebelum ini. Tempoh lawatan susulan kesan sampingan akan berdasarkan budi bicara penyelidik dan kajian pasukannya.

Kesan produk kajian terhadap anak yang belum lahir masih tidak lagi diketahui. Oleh itu, peserta perempuan tidak harus menyusukan bayi semasa dalam kajian ini kerana produk kajian mungkin terdapat di dalam susu ibu. Anda juga tidak boleh mengandung atau menyebabkan pasangan anda mengandung semasa dalam kajian ini. Wanita yang subur akan diberi ujian kehamilan untuk mengesahkan bahawa mereka tidak hamil. Semasa dalam kajian, ianya adalah penting bahawa anda menggunakan kaedah kontrasepsi kelahiran yang sangat berkesan secara konsisten dan betul; doktor penyelidikan akan membincangkan kaedah ini dengan anda. Sila maklumkan kepada penyelidik dengan segera jika anda atau pasangan anda telah hamil semasa dalam kajian ini. Jika anda hamil, rawatan kajian ini akan dihentikan dengan serta-merta dan anda tidak boleh lagi menyertai kajian ini. Tetapi kami akan terus memantau kehamilan anda sehingga kelahiran anak anda untuk memastikan kesihatan anda dan bayi anda.

Memandangkan komputer akan memberikan kod identiti yang tidak boleh diketahui oleh sesiapa kepada anda secara rawak, risiko untuk kejadian pendedahan maklumat peribadi anda adalah sangat minimum. Kami juga akan memaklumkan kepada anda dengan segera sekiranya terdapat sebarang penemuan baru atau perubahan mengenai produk kajian yang

boleh menjejaskan kesihatan atau kerelaan anda untuk meneruskan kajian ini. Jika perlu, anda mungkin akan diminta untuk memberi kebenaran semula untuk mengambil bahagian dalam kajian ini.

Penyelidikan yang melibatkan ujian diagnostik atau kemungkinan hasil sampingan

Kami biasanya akan bertanya kepada peserta kami jika mereka ingin dimaklumkan tentang (i) sebarang penemuan diagnostik, (ii) penemuan sampingan dan/atau (iii) hanya penemuan buruk yang disebabkan oleh rawatan kajian. Anda juga akan menentukan sama ada sebarang penemuan ini boleh dibincangkan dengan doktor keluarga anda, doktor lain pilihan anda, atau salah seorang daripada ahli pasukan kami.

Sekiranya anda telah bersetuju dengan mana-mana pilihan di atas, pasukan penyelidikan kami akan memaklumkan anda dengan sewajarnya sepanjang penyelidikan ini. Tetapi anda tidak akan dimaklumkan jika anda mengambil ubat aktif (100mg Tocovid atau 200mg Tocovid) atau ubat tidak aktif (plasebo) kerana ianya akan menjejaskan hasil kajian kami.

Bayaran ganjaran

Anda akan dibayar sebanyak RM30 bagi setiap lawatan untuk perbelanjaan perjalanan anda ke Pusat Penyelidikan Klinikal kami, walaupun jika anda memilih untuk melaksanakan sebahagian daripada penyelidikan atau anda menarik diri dari penyelidikan lebih awal.

Kerahsiaan data peribadi dan maklumat kajian

Sifat penyelidikan ini memerlukan pengumpulan butir-butir peribadi daripada anda melalui temu duga tentang sejarah perubatan, pemeriksaan fizikal dan ujian-ujian. Namun begitu, hanya maklumat yang berkaitan dengan kelayakan anda untuk menyertai kajian ini akan diperolehi. Apabila sudah direkrut, identiti anda hanya dapat dikenal pasti melalui nombor subjek kajian anda. Nombor ini tidak akan mempunyai sebarang kaitan dengan maklumat peribadi anda yang boleh mendedahkan identiti anda. Setiap nombor adalah unik dan hanya boleh diakses oleh penyiasat kajian ini. Senarai induk yang mengandungi butir-butir anda hanya akan dapat diakses oleh Ketua Penyelidik. Pengumpulan data dan analisis seterusnya hanya akan menggunakan nombor peserta kajian. Senarai induk kajian ini akan dimusnahkan sebaik sahaja kajian ini diterbitkan.

Segala maklumat peribadi anda yang diperolehi daripada kajian ini akan akan disimpan dan dikendalikan secara sulit, mengikut undang-undang dan peraturan yang berkenaan. Apabila hasil kajian diterbitkan atau dibentangkan, identiti anda tidak akan didedahkan tanpa kebenaran anda. Penyiasat kajian ini, pemantau atau juruaudit yang berkelayakan, penaja atau sekutunya dan pihak berkuasa kerajaan atau pengawal selia boleh memeriksa dan menyalin rekod perubatan anda, jika sesuai dan diperlukan.

Data dari kajian akan diarkibkan dan boleh dihantar ke luar negara untuk tujuan analisis, tetapi identiti anda tidak akan didedahkan pada bila-bila masa.

Kaedah penyimpanan data

Data yang dikumpul untuk kajian ini akan disimpan dalam fail kajian kami di dalam kabinet berkunci dalam sebuah bilik berkunci di Pusat Penyelidikan Klinikal kami. Setelah kajian ini tamat, semua butir-butiran dalam fail kajian akan disimpan dan ditangani oleh Monash University Malaysia sekurang-kurangnya 15 tahun selepas tamat penyelidikan.

Semua sampel darah yang diperolehi daripada anda akan digunakan untuk mengenal pasti penanda biologi untuk nefropati, retinopati dan neuropati diabetik. Beberapa mililiter sampel darah anda akan disimpan oleh pasukan penyiasat selama 2 tahun untuk membuat ujian penanda biologi yang lain pada masa depan apabila mempunyai dana. Tiada ujian genetik akan dilakukan pada biospesimen anda. Biospesimen anda akan diberi kod yang tidak mendedahkan identiti anda. Hanya pasukan kami boleh menghubungkan kod tersebut dengan anda. Penyiasat kajian ini boleh berkongsi biospesimen anda dengan penyelidik lain tetapi identiti anda akan dirahsiakan. Anda boleh menarik balik kebenaran anda dan biospesimen anda akan dimusnahkan tetapi sebarang maklumat yang telah diperolehi daripada biospesimen anda boleh digunakan untuk penyelidikan ini.

Penggunaan data untuk tujuan lain

Data yang dikumpulkan untuk kajian ini tidak akan digunakan untuk sebarang kajian lain pada masa hadapan tanpa kelulusan terlebih dahulu daripada badan pengawal seliaan yang berkaitan dan/atau jawatankuasa etika. Harap maklum bahawa hanya data agregat yang tidak boleh dikenal identitinya akan digunakan untuk projek lain di mana kelulusan etika telah diberikan.

Keputusan Kajian

Keputusan kajian ini akan dimaklumkan pada akhir tahun depan. Jika anda ingin mengakses keputusan ujian anda sepanjang penyelidikan ini, anda boleh menghubungi pasukan penyiasat kami melalui telefon, e-mel atau menghadirkan diri ke Pusat Penyelidikan Klinikal kami.

Aduan tentang Kajian

Sekiranya anda mempunyai sebarang kebimbangan atau aduan mengenai projek ini, anda dialu-alukan untuk menghubungi Timbalan Ketua Sekolah (Penyelidikan Siswazah), Jeffrey Cheah School of Medicine and Health Sciences, Monash University Malaysia:

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Sekian, Terima Kasih

Profesor Dato' Dr Khalid Abdul Kadir

Ketua Penyelidik

Jeffrey Cheah School of Medicine and Health Sciences,
Monash University Malaysia.

Appendix V: Informed Consent (Malay)

BORANG KEBENARAN (LAMPIRAN PESERTA)

Projek: Kesan Dosis Rendah Vitamin E yang Kaya dengan Tokotrienol daripada Minyak Kelapa Sawit (Tocovid SupraBio®) dan Alfa-Tokoferol terhadap Diabetes dan Komplikasi

Mikrovaskular Diabetes: Nefropati (Buah Pinggang), Retinopati (Mata) dan Neuropati (Urat Saraf)

Ketua Penyelidik: Profesor Dato' Dr Khalid Abdul Kadir

Saya telah diminta untuk mengambil bahagian dalam projek penyelidikan Universiti Monash yang dinyatakan di atas. Saya telah membaca dan memahami Kenyataan Penyelidikan dan saya bersetuju untuk mengambil bahagian dalam projek ini.

Saya bersetuju dengan yang berikut:	Ya	Tidak
1. Sampel data/tisu yang saya berikan semasa penyelidikan ini akan disimpan selama 2 tahun dan boleh digunakan oleh pasukan penyelidik untuk menguji penanda biomolekil lain dalam projek penyelidikan pada masa hadapan.		
2. Sekiranya terdapat penemuan maklumat baru, saya ingin dinasihatkan tentang:		
(a) Sebarang penemuan diagnostik		
(b) Sebarang penemuan sampingan		
(c) Hanya penemuan mudarat/buruk yang secara langsung disebabkan oleh rawatan kajian		
3. Sekiranya terdapat penemuan maklumat baru, saya ingin dinasihatkan dan berbincang tentang sebarang penemuan diagnostik/sampingan/mudarat(buruk) dengan:		
(a) Doktor keluarga saya		
(b) Doktor pilihan saya		
(c) Atau salah seorang dari ahli penyelidik dari pasukan kami		

Peserta:

Tandatangan: **Nombor K/P:**

Nama: **Tarikh:**

Penyelidik yang mengendalikan proses menandatangani keizinian:

Tandatangan: **Nombor K/P:**

Nama: **Tarikh:**

BORANG KEBENARAN (LAMPIRAN PENYELIDIK)

Projek: Kesan Dosis Rendah Vitamin E yang Kaya dengan Tokotrienol daripada Minyak Kelapa Sawit (Tocovid SupraBio®) dan Alfa-Tokoferol terhadap Diabetes dan Komplikasi

Mikrovaskular Diabetes: Nefropati (Buah Pinggang), Retinopati (Mata) dan Neuropati (Urat Saraf)

Ketua Penyelidik: Profesor Dato' Dr Khalid Abdul Kadir

Saya telah diminta untuk mengambil bahagian dalam projek penyelidikan Universiti Monash yang dinyatakan di atas. Saya telah membaca dan memahami Kenyataan Penyelidikan dan saya bersetuju untuk mengambil bahagian dalam projek ini.

Saya bersetuju dengan yang berikut:	Ya	Tidak
1. Sampel data/tisu yang saya berikan semasa penyelidikan ini akan disimpan selama 2 tahun dan boleh digunakan oleh pasukan penyelidik untuk menguji penanda biomolekil lain dalam projek penyelidikan pada masa hadapan.		
2. Sekiranya terdapat penemuan maklumat baru, saya ingin dinasihatkan tentang:		
(a) Sebarang penemuan diagnostik		
(b) Sebarang penemuan sampingan		
(c) Hanya penemuan mudarat/buruk yang secara langsung disebabkan oleh rawatan kajian		
3. Sekiranya terdapat penemuan maklumat baru, saya ingin dinasihatkan dan berbincang tentang sebarang penemuan diagnostik/sampingan/mudarat(buruk) dengan:		
(a) Doktor keluarga saya		
(b) Doktor pilihan saya		
(c) Atau salah seorang dari ahli penyelidik dari pasukan kami		

Peserta:

Tandatangan: **Nombor K/P:**

Nama: **Tarikh:**

Penyelidik yang mengendalikan proses menandatangani keizinian:

Tandatangan: **Nombor K/P:**

Nama: **Tarikh:**