*Southern Adelaide Local Health Network*

**Participant Information Sheet/Consent Form**

**Non-Interventional Study** -*Adult providing own consent*

*Southern Adelaide Local Health Network*

|  |  |
| --- | --- |
| **Title** | Blood sugar testing for diabetes in people on prednisolone |
| **Coordinating Principal Investigator/ Principal Investigator** | A/Prof Morton Burt |
| **Location** | Southern Adelaide Local Health Network |

**Part 1 What does my participation involve?**

1. **Introduction**

You are invited to take part in this research project, Optimum diagnostic testing for prednisolone induced hyperglycaemia. This is because you are currently taking prednisolone at a dose of ≥4 mg / day. This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want to take part in the research.Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local doctor.Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. You will receive the best possible care whether or not you take part.If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

• Consent to the tests and research that are described

• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

**2 What is the purpose of this research?**

Our aim is to investigate whether measuring an afternoon random blood glucose level is more effective at diagnosing high blood glucose levels that cause diabetes in patients taking prednisolone than measuring fasting blood glucose (glucose measured in the morning before you have eaten). These two methods of testing for diabetes will be compared to an oral glucose tolerance test, which is the most accurate test to diagnose diabetes. An oral glucose tolerance test involves measuring a fasting level of blood glucose in the morning, and seeing how much the glucose level rises after you drink a drink containing 75 grams of glucose. These glucose levels are then interpreted to determine if you have diabetes.

Prednisolone, even at low doses, can increase blood glucose and cause diabetes. Previous research conducted by the Southern Adelaide Local Health Network, reported that 15% of patients taking prednisolone have diabetes. However, as prednisolone mainly increases blood glucose after eating, many patients are not diagnosed with diabetes by measuring fasting glucose.

We predict that measuring blood glucose in the afternoon may be a good diagnostic test for diabetes in patients prescribed prednisolone. However, currently there is no published research assessing whether measuring afternoon glucose is better than measuring fasting glucose in patients taking prednisolone.

If it can be demonstrated that an afternoon random blood glucose is superior to a fasting blood glucose, this will represent a simple convenient test to diagnose diabetes in patients prescribed prednisolone.

The results of this research will be used by the study doctor Dr Faran Khalilito obtain a Master of Science by Research.

This research has been initiated by the Principal Investigator – A/Prof Morton Burt

**3 What does participation in this research involve?**

Your signed consent will first be obtained prior to any assessment or investigation being performed. Once you consent to participating in this study, you will attend the Endocrine Research Unit for an Oral Glucose Tolerance Test. On a separate day, you will go to a SA Pathology between 2 pm and 5 pm for measurement of a random afternoon blood glucose.

The Oral Glucose Tolerance Test is most accurate if you eat a reasonable amount of carbohydrate in the 3 days before the test. Information about the amount of carbohydrate that should be eaten is found at the end of this information sheet (appendix 1).

You will need to have nothing to eat or drink other than water after 10 pm on the night before the Oral Glucose Tolerance Test. You can take all your medications with water on the morning of the test. **In particular, please take your prednisolone as usual on the morning of the test.**

In the morning at 9 am, an intravenous cannula (small plastic tube) will be inserted into your arm and a blood sample will be collected to measure fasting blood glucose. At the time of measuring fasting glucose additional blood samples will be collected to measure inflammation levels in the body, insulin, cholesterol, kidney function, liver function and glycosylated haemoglobin (which is an estimate of your glucose levels over the last 3 months).

We will also ask if you consent to the investigators storing an sample of blood for possible measurement of prednisolone activity and other cardiovascular risk markers that can be measured in blood. This is to determine if the investigators can identify a biochemical marker in participants taking prednisolone which may predict the risk of developing diabetes. The storing of an sample of blood is voluntary and you may elect to not participate in this part of the study.

After the fasting blood test you will then be given a drink containing 75 g glucose. A second blood sample will be collected out of the same intravenous cannula 2 hours after drinking the glucose drink. While you are waiting for the second blood test we will ask you some questions about your health and the medications you are taking and will measure your weight, height, waist and hip circumference. We will review your medical record to obtain additional information about your health problems.

You are required to remain on site at Marion GP Plus for the duration of the Oral Glucose Tolerance Test which is 2 hours.

On a separate day, you will be asked to attend a blood collecting centre for SA Pathology between 2 pm and 5 pm for a random afternoon glucose measurement.

A copy of the results obtained in this study will be sent to your General Practitioner or Primary Physician and we will ask your General Practitioner to follow-up any abnormal results.

Audio and Video will not be taken as part of this research

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are no costs associated with participating in this research project, nor will you be paid.

It is desirable that your local doctor be advised of your decision to participate in this research project. If you have a local doctor, we strongly recommend that you inform them of your participation in this research project.

**4 What do I have to do?**

Apart from the instructions regarding carbohydrate intake outlined in this Information Sheet, there are no lifestyle restrictions required to participate in this study. You are to continue taking your regularly prescribed medications. Participating in this test does not impact on your desire to donate blood in the future.

You will undergo an Oral Glucose Tolerance Test and on separate day, undertake a random afternoon blood glucose.

**5 Other relevant information about the research project**

This project will be conducted only within the Southern Adelaide Local Health Network

(SALHN). We are aiming to recruit a minimum of 100 participants for this study.

**6 Do I have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Southern Adelaide Local Health Network

**7 What are the alternatives to participation?**

If you do not participate in this study you will continue to be cared for by your General Practitioner and physician as usual.

**8 What are the possible benefits of taking part?**

We cannot guarantee or promise that you will receive any benefits from this research, however possible benefits may include;

1. Diagnosing Diabetes which will enable you to obtain appropriate treatment if required.
2. This research may enable us to identify a more simple, less time consuming and cost effective, mode of diagnosing diabetes in patients taking prednisolone

**9 What are the possible risks and disadvantages of taking part?**

Insertion or an intravenous cannula and providing a blood sample taken may cause some discomfort, fainting, bruising, infection or bleeding . If this happens, it can be easily treated.

The glucose drink for the Oral Glucose Tolerance Test can cause some nausea.

If you experience any of the above symptoms, then please inform a trial investigator who will be present for the duration of your time at Marion GP Plus.

**10 What will happen to my test samples?**

The collection of your blood samples is a mandatory component of your participation in this research. Your blood sample will be used for research purposes in this project (as mentioned above) and a sample will also be stored and frozen securely in our research facility at Marion GP Plus. Your blood sample will be stored in the event that additional testing of metabolic and cardiovascular risk markers is required in the future.

No genetic testing will be performed on your blood samples.

Should you wish to withdraw your consent from the storage of a blood sample, then please inform one of the trial investigators your sample will be withdrawn and not included in any part of the study’s results.

Samples of your blood obtained for the purpose of this research project will be stored at Marion GP Plus and will not be sold by the Southern Adelaide Local Health Network

**11 What if I withdraw from this research project?**

If you decide to withdraw from this research project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing.

**12 Could this research project be stopped unexpectedly?**

This research project may be stopped unexpectedly for a variety of reasons. These may include relocation of the chief investigators and an insufficient number of participants recruited for the study.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the investigators up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

**13 What happens when the research project ends?**

When this research project ends, the investigators will write a summary of the results. You will be invited to attend an optional seminar where the trial investigators will give a presentation on the results of the study. A family member may attend with you if you wish. You will also have the option of being provided with a project summary if you would like to have one.

Attending the seminar will make it clear that you are a participant in this study to other participants that are attending and either currently or previously taking prednisolone.

If you would like to attend the seminar and/or receive a copy of the project summary results, please tick the relevant box in the patient signature page

If you would like to attend this seminar, please inform one of the trial team members. We anticipate this project to be completed within 3 years.

**Part 2 How is the research project being conducted?**

**14 What will happen to information about me?**

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

The research data is not identifiable and will be stored on a secure, password protected server of the Southern Adelaide Local Health Network (SALHN)

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the research team accessing health records if they are relevant to your participation in this research project.

Your General Practitioner and treating specialist will be provided with a summary of your blood test. By consenting to participate in this study, you are also consenting to the investigators to inform your General Practitioner and treating specialist to be informed of your blood test results. These include both normal, or any abnormal findings.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. Your name will not be used in any published research or presentation.

In accordance with relevant Australian privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project and for the future research described in Section 16 that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

**15 Complaints and compensation**

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

Consenting to participate in this study does not mean a participant cannot pursue compensation through the courts if they are harmed or injured during the study.

**16 Will I be charged a fee for parking and will I be reimbursed if I require a taxi for transport to Marion GP Plus**

There is free public parking available on site and if you require a taxi to and from Marion GP plus, then a taxi voucher covering the full cost of the travel to and from the centre will be provided.

**17 Who is organising and funding the research?**

This research project is being conducted by Associate Professor Morton Burt, Professor Michael Shanahan and Dr Faran Khalili

You will not benefit financially from your involvement in this research project even if, for example, your samples (or knowledge acquired from analysis of your samples) prove to be of commercial value to Flinders University.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

**18 Will I have to pay a fee to be involved in this research?**

You will not incur a cost to participate in this research. The cost of the blood tests and the storage of a sample of your blood will be covered by the trial investigators.

**19 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the Southern Adelaide Clinical Human Research Ethics Committee

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**22 Further information and who to contact**

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the study clinical contact person

**Clinical contact person (during business hours 8am – 5 pm)**

|  |  |
| --- | --- |
| Name | Dr Faran Khalili |
| Position | Study Investigator |
| Telephone | Southern Adelaide Diabetes Services - (08) 7425 8690 |
| Email | Faran.khalili@sa.gov.au |

**Clinical contact person out of hours (5 pm – 8am)**

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| Name | Endocrine Registrar on call |
| Telephone | Flinders Medical Centre – 8204 5511 |
| Email | Faran.khalili@sa.gov.au |

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

|  |  |
| --- | --- |
| Name | Simon Windsor |
| Position | Manager, Research Governance and Ethics |
| Telephone | *82046453* |
| Email | *Health.SALHNOfficeforResearch@sa.gov.au* |

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

|  |  |
| --- | --- |
| Reviewing HREC name | Southern Adelaide Clinical |
| HREC Executive Officer | *Executive Officer* |
| Telephone | *82046453* |
| Email | *Health.SALHNOfficeforResearch@sa.gov.au* |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

**Local HREC Office contact (Single Site -Research Governance Officer)**

|  |  |
| --- | --- |
| Name | *Southern Adelaide Local Health Network* |
| Position | *Research Governance Officer* |
| Telephone | *82046453* |
| Email | *Health.SALHNOfficeforResearch@sa.gov.au* |

**Consent Form -** *Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | Blood sugar testing for diabetes in people on prednisolone |
|  |  |
| **Coordinating Principal Investigator/**  **Principal Investigator** | A.Prof Morton Burt |
| **Associate Investigator(s)** | Professor Michael Shanahan, Dr Faran Khalili, Prof Richard Woodman, Ms Sophie Drake, Ms Kellie Fusco |
| **Location** | Southern Adelaide Local Health Network |

**Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

I would like to attend the optional seminar where the trial investigators will give a presentation on the results of the study

Yes

No

I would like a copy of the project summary results once the study has completed

Yes

No

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|  | | | | | | |
|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
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|  | Name of Witness\* to Participant’s Signature (please print) | |  | | |  | |
|  | | | | | | | |
|  | Signature |  | | Date |  | |  | |
|  | | | | | | | |

\* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project; its procedures and risks and I believe that the participant has understood that explanation.

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|  | Name of Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
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† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

**Consent Form -** *Adult providing own consent*

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| --- | --- |
| **Collection** | Blood sugar testing for diabetes in people on prednisolone |
|  |  |
| **Coordinating Principal Investigator/**  **Principal Investigator** | A.Prof Morton Burt |
| **Associate Investigator(s)** | Profssor Michael Shanahan, Dr Faran Khalili, Prof Richard Woodman, Ms Sophie Drake, Ms Kellie Fusco |
| **Location** | Southern Adelaide Local Health Network |

**Declaration by Participant**

I also consent to the investigators, storing an a sample of blood for further analysis of glucocorticoid activity as outlined in the participant information sheet

I understand the purposes, procedures and risks of the research described in the project.

I may withdraw my consent to the storage of an sample of blood at any time during the project without affecting my future health care

I understand that I will be given a signed copy of this document to keep.

|  |  |  |  |  |  |  |
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|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
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|  | Name of Witness\* to Participant’s Signature (please print) | |  | | |  | |
|  | | | | | | | |
|  | Signature |  | | Date |  | |  | |
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\* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project; its procedures and risks and I believe that the participant has understood that explanation.

|  |  |  |  |  |  |  |
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|  | Name of Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signatur

**Form for Withdrawal of Participation -** *Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | Optimum diagnostic testing for prednisolone-  induced hyperglycaemia |
| **Protocol Number** |
| **Project Sponsor** |
| **Coordinating Principal Investigator/**  **Principal Investigator** | A.Prof Morton Burt |
| **Associate Investigator(s)** | Prof Michael Shanahan, Dr Faran Khalili, Prof Richard Woodman, Ms Sophie Drake, Ms Kellie Fusco |
| **Location** | Southern Adelaide Local Health Network |
| **Title** | Optimum diagnostic testing for prednisolone-  induced hyperglycaemia |

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with.

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|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
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**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

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|  | | | | | | |
|  | Name of Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.