Participant Information Sheet/Consent Form

Interventional Study *-Adult providing own consent*

Sinclair Dermatology

Title	Hidradenitis suppurativa treated with follicular unit extraction: A prospective comparator 24-week pilot study
Short Title	Hidradenitis suppurativa treated with follicular unit extraction: A prospective comparator 24-week pilot study
Protocol Number	FUEHS001
Project Sponsor	The Royal Melbourne Hospital
Coordinating Principal Investigator/ Principal Investigator	Dr Bevin Bhoyrul
Associate Investigator(s)	
Location	Level 3, 2 Wellington Parade East Melbourne, VIC 3002

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you have mild to moderate hidradenitis suppurativa (HS). This research project is testing a procedural technique, FUE (Follicular Unit Extraction), as a treatment for hidradenitis suppurativa.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you would like to take part in the research.

Please read this information carefully. Please ask questions about anything that you do not understand or want to know more about. Before deciding whether or not to take part, you may wish to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you do not wish to take part, you do not 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 have the tests and treatments that are described
• Consent to the use of your samples, 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?

This research aims to assess whether or not FUE can improve symptoms of HS in comparison to topical clindamycin, which is an antibiotic used to manage HS in routine standard care. The FUE procedure has been used as a treatment in other parts of dermatology such as hair transplants but to date, there has been no studies to show whether or not this treatment works for hidradenitis suppurativa.

This research has been initiated by the study team member, Dr Bevin Bhoyrul at Sinclair Dermatology. Dr Bevin Bhoyrul is also the principal investigator in this study.

3 What does participation in this research involve?

We would need your agreement and signature on the consent form before doing any study assessments. All study assessments will be conducted at Sinclair Dermatology.

FUE is a procedural technique that remove hair follicle units with the surrounding eccrine, apocrine and sweat glands under local anaesthetic. It has been used over many years to extract hair follicles from the scalp for hair transplantation and can extract hairs from other parts of the body as well. It has been used for some dermatological conditions including vitiligo. We believe that FUE may be beneficial in improving symptoms for HS because HS causes inflammation of the hair follicles and the surrounding glands. Therefore, if these structures are removed, then there won't be inflammation causing symptoms.

There are two groups in this study – one group will receive FUE while the other group will receive topical clindamycin. The purpose of the two groups is so that we can assess the efficacy of FUE. Assignment to the intervention group (i.e. FUE) and comparator group (i.e. receiving topical clindamycin) will be determined by numbers generated from 1 to 24. You will be given a number based on chronological order of recruitment which determines which group you are in.

There are 4 visits. However in general, these visits are part of standard routine care and follows the frequency of when we assess your hidradenitis suppurativa when we commence treatment.

Your initial visit will be the initial consultation visit where you discuss your HS symptoms and discuss potential treatment options. This is when we can discuss with you about treatments such as the topical treatment and FUE, as well as screen to see if this study is suitable for you. Your first study visit will occur within 28 days of the screening, or the screening can be done on the same day as the first visit provided that you have been given adequate time to read the patient consent form, provided enough details as well as have your questions answered

adequately. If you are in the FUE group, in this visit, you will go to a procedure room and local anaesthetic will be injected to the site of HS flare, either in your axilla or groin on both right and left side. Your treating specialist (who has expertise in FUE) will extract the hair follicles and surrounding glands. These samples will be analysed to confirm complete removal of the hair follicles and the surrounding structures. The samples will then be discarded. If you are in the group receiving topical clindamycin, you will be given supplies of topical clindamycin as part of standard routine care which will last you for the duration of the treatment. Your second visit will include a review of your HS, as part of your standard care, 6 weeks after your procedure. These treatments will be free of charge regardless of which group you are in.

You are participating in a comparison study. We are extracting hair follicles from both sites of either your underarm or groin. You will either be allocated to the intervention group or the comparison group. Regardless of which group you are in you will receive treatment for your HS. This is to see whether or not FUE is effective.

Details of tests and procedures to be undertaken at each study visit are outlined below

Screening

You will be screened prior to enrolment in the study. The following procedures must be conducted at the screening visit – this may be in your initial consult as part of standard care:

- Written informed consent
- Review of eligibility (diagnosis, inclusion and exclusion criteria)
- Medical history (including previous psoriasis treatments)
- Physical Examination
- Vital Signs (Respiratory rate, heart rate, temperature, blood pressure)
- Weight
- Height
- HS severity score

Visit 1 (Week 0)

This visit occurs no later than 28 days from Screening visit. The visit may occur on the same day as the screening visit provided i) you have been given sufficient time to read through the patient information and consent form and ii) seek advice from your primary physician, family and/or friend and iii) have had your questions answered by the investigator adequately.

- Review of inclusion and exclusion criteria
- Review of medical history
- Review of adverse events (if any)
- Concomitant medication collection
- Vital Signs (Respiratory rate, heart rate, temperature, blood pressure)

- Physical Examination
- Weight
- Review of HS progress
- Follicular unit extraction and sample analysis (if intervention group)
- Providing topical resorcinol/clindamycin (if comparison group)
- HS severity score assessment – we will assess your underarms or groins to count lesions, this includes counting the total number of active nodules, abscesses, blackheads and any sinus tracts that formed as part of HS.

Visit 2 (Week 6)

- Review of withdrawal criteria – we will assess whether there have been any changes in your medical condition (such as pregnancy if relevant or worsening HS) to see whether or not you can continue this study.
- Review of adverse events (if any)
- Review of HS progress
- Concomitant medication collection
- Vital Signs (Respiratory rate, heart rate, tympanic temperature, blood pressure)
- Physical Examination
- HS severity score assessment – we will assess your underarms or groins to count lesions, this includes counting the total number of active nodules, abscesses, blackheads and any sinus tracts that formed as part of HS.
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Visit 3 (Week 12)

- Review of adverse events (if any)
- Review of HS progress
- Concomitant medication collection
- Vital Signs (Respiratory rate, heart rate, tympanic temperature, blood pressure)
- Physical Examination
- HS severity score assessment – we will assess your underarms or groins to count lesions, this includes counting the total number of active nodules, abscesses, blackheads and any sinus tracts that formed as part of HS.

Visit 4 (Week 24)

- Review of adverse events (if any)
- Review of HS progress
- Concomitant medication collection

- Vital Signs (Respiratory rate, heart rate, temperature, blood pressure)
- Physical Examination
- HS severity score assessment – we will assess your underarms or groins to count lesions, this includes counting the total number of active nodules, abscesses, blackheads and any sinus tracts that formed as part of HS.

At the end of the week 24 visit, your participation in the study is over. You will still receive ongoing care.

The two treatments being compared in this research project - The FUE procedure and the topical clindamycin treatment - will be provided free of charge. You will not be paid for your participation in this research project.

If you are in the comparison group, you will be given clindamycin to apply to affected area. At each study visit you will be asked about how many flareup episodes you have and where that flare up occurred (e.g. arm or groin, left side or right side).

If you decide to participate in this research trial, the study team member, with your consent, will inform your local doctor. We encourage your local doctor to continue to be involved in your care. The consent may be done on paper.

The hair follicles extracted will be reviewed under the microscope on the same day to ensure that we have removed them entirely. Afterwards, the specimens will be discarded into the biohazard waste bin.

4 What do I have to do?

After screening, you will attend the first visit during which you will either have the FUE procedure or be given the topical clindamycin, depending on which treatment group you have been allocated to. you will be given the topical clindamycin in the first visit instead. You are under no obligation, to participate in this research project. If at any time you change your mind and no longer wish to be involved in the research trial then this will not affect your ongoing care.

At each study visit, you will be asked about how many flare-up episodes you have had since your last visit. To help you, you will be given a diary sheet where you can record the date and time that any flare ups occur, where they occurred on your body as well as rating any pain or discomfort on a scale of one to10. You may choose to also take a photo to show to the researchers if you like. We will not need to collect photos from you but we can have a look at the photos taken at the study visit as this information will help us assess the severity of your flareups.

There are no other lifestyle or dietary restrictions. Your treating doctor may ask you not to take certain medications before the procedure as well as give you instructions pre-procedure as part of standard routine care.

If you need to commence any new medications or have other procedures/surgeries done while the research trial is being conducted, please let the study doctor know.

It is your responsibility to inform the study team members immediately if there are any issues or concerns during clinical visits or tests performed, as we can assist you with these issues.

The schedule of this research trial is as shown below:

Study schedule/visits.

Assessment/Procedure	Screening (Initial assessment)	Visit 1 (may occur same day as screening visit)	Visit 2	Visit 3	Visit 4
Demographic information and eligibility: - Inclusion/exclusion criteria - Height and weight - Medical History - Concomitant medications - Weight	X				
Consent	X	X			
Medical History and concomitant medications review		X	X	X	X
Clinical assessments (as part of standard routine care)	X	X	X	X	X
Follicular unit extraction and sample analysis (if in intervention group)		X			
Topical resorcinol/clindamycin (if in comparison group)		X			
Hidradenitis suppurativa assessment score	X	X	X	X	X

5 Other relevant information about the research project

This study will be conducted at Sinclair Dermatology. Overall, there will be 24 participants in the 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 Sinclair Dermatology.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment. Other management options are available for your care. Your study team member will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research. In this research trial, we may find results that suggest FUE is beneficial in reducing severity of HS for a certain period of time. Hence, improvement in HS for a certain period of time does not mean you will not experience HS progression in the future. Other possible benefits may include improving clinical guidelines and management options for HS.

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

Your treating doctor will explain the risks of the FUE procedure to you if you are allocated to receive FUE treatment. Some risks include: pain, bleeding, infection, cosmetic dissatisfaction of treated site and failure of FUE to improve symptoms. If you are in the group receiving topical clindamycin, we will explain to you how to apply it as well as the expected side-effects as part of standard care. Common side effects of topical clindamycin include dryness, scaliness or peeling of skin, abdominal pain, mild diarrhoea, headache, irritation of the skin or burning sensation of the skin.

If you are concerned about these side effects, talk with your treating doctor. Your treating doctor will also be looking out for side effects as part of standard routine follow-up.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your treating doctor immediately about any new or unusual symptoms that you get.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, let your treating doctor know. Your treating doctor will discuss the best way of managing any side effects with you.

If your participation in this research uncovers a medical condition of which you were unaware of, we will support you in accessing appropriate information and management.

It is important you continue to follow medical advice given to you while participating in this clinical study.

If you become upset or distressed as a result of any part of your participation in the research, let the treating doctor know.

10 What will happen to my test samples?

We do not collect any test samples. FUE involves extraction of hair follicles and glands – these will be analysed under a microscope, and documented only for the purpose of confirming that these have been completely removed. The samples will be discarded. They will not be used for other analyses nor will they be kept for other current or future research.

Data collected for this research will be retained for at least 5 years and then destroyed.

11 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your treating doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your treating doctor will make arrangements. Also, on receiving new information, your treating doctor might consider it to be in your best interest to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

12 Can I have other treatments during this research project?

Whilst you are participating in this research project, you may not be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. It is important to tell your dermatologist about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your treating doctor about any changes to these during your participation in the research project. Your treating doctor should also explain to you which treatments or medications need to be stopped for the time you are involved in the research project.

It may also be necessary for you to take medication during or after the research project to address side effects or symptoms that you may have. You may need to pay for these medications and so it is important that you ask your doctor about this possibility.

13 What if I withdraw from this research project?

If you decide to withdraw from this research project, please notify the treating doctor before you withdraw. We will inform you if there are any special requirements linked to withdrawing.

If you do withdraw your consent during the research project, your study doctor or 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 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.

14 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:
• Unacceptable side effects
• Risks of FUE outweighs the benefit
• Decisions made by local regulatory/health authorities.

15 What happens when the research project ends?

At the conclusion of this study, you will continue to be managed as part of your standard routine care.

The results of the study may be published in academic journals. You will not be identified in these publications. The research staff can let you know the results of the study when they are available.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

By signing the Consent Form, you consent to the study team member 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 and securely stored. Only the researchers named above will have access to it and it will only be disclosed with your permission. Electronic information such as this will be stored on a password protected computer system at Sinclair Dermatology. Your paper and electronic data will be stored for 5 years following completion of this study. At the end of 5 years, any information that does not also form part of your medical record will be permanently destroyed (deleted or shredded). Your data will be stored safely on an excel sheet which is password-encoded, in a password-protected area of the server within Sinclair Dermatology. Only the investigators will have access to this data.

Information about you may be obtained from your health records held at this and other health services including your GP clinic 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 health records and any information obtained during the study are subject to inspection (for the purpose of verifying the procedures and the data) by the Australian Government's Therapeutic Goods Administration (TGA), or Human Research Ethics Committee, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

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 presented in such a way that you cannot be identified, except with your permission. This is because results will be published in aggregate only and include no features that could identify any individual participant. Information about your participation in this research project may be recorded in your health records.

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

Any information obtained for the purpose of this research project and for future research 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.

17 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. You can also speak to a consumer liaison officer at the Centre for Patient Experience by calling (03) 9496 3566.

18 Who is organising and funding the research?

This research project is being conducted by Dr Bevin Bhoyrul. This research is not commercially nor pharmaceutically funded. Dr Bevin Bhoyrul will bear the costs for this study.

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.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to Sinclair Dermatology, the study team members or their institutions, there will be no financial benefit to you or your family from these discoveries.

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 Human Research Ethics Committee of The Royal Melbourne Hospital.

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.

20 Further information and who to contact

Clinical contact person

Name	Dr Bevin Bhoyrul
Position	Chief Investigator
Telephone	03 9654 2426
Email	Bevin.Bhoyrul@sinclairdermatology.com.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	Office for Research: Manager Human Research Ethics committee
Position	Manager of HREC
Telephone	03 9342 7602
Email	research@mh.org.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 approving this research and HREC Executive Officer details

Reviewing HREC name	Office for Research: Manager Human Research Ethics committee
Position	Manager of HREC
Telephone	03 9342 7602
Email	research@mh.org.au

Consent Form - *Adult providing own consent*

Title	Hidradenitis suppurativa treated with follicular unit extraction: A prospective comparator pilot study
Short Title	Hidradenitis suppurativa treated with follicular unit extraction: A prospective comparator pilot study
Protocol Number	1.2
Project Sponsor	
Coordinating Principal Investigator/ Principal Investigator	Dr Bevin Bhoyrul
Associate Investigator(s)	
Location	Level 3, 2 Wellington parade East Melbourne, VIC 3002

Consent Agreement

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 give permission for my doctors, other health professionals, hospitals or laboratories outside Sinclair Dermatology to release information to Sinclair Dermatology concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

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 study without affecting my future health care.

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

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

Declaration by Participant – for participants who have read the information

Name of Participant (please print) _____

Signature _____ Date _____

Declaration - for participants unable to read the information and consent form
Witness to the informed consent process
Name (please print) _____

Signature _____ Date _____
* Witness is not to be the Investigator, a member of the study team or their delegate. 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.

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 signature.

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

Name of Participant (please print) _____

Signature _____ Date _____

For participants unable to read the information and consent form
Witness to the informed consent process
Name (please print) _____
Signature _____ Date _____
* Witness is not to be the Investigator, a member of the study team or their delegate. Witness must be 18 years or older.

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 signature

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

Title	Hidradenitis suppurativa treated with follicular unit extraction: A prospective comparator pilot study
Short Title	Hidradenitis suppurativa treated with follicular unit extraction: A prospective comparator pilot study
Protocol Number	1.2
Project Sponsor	
Coordinating Principal Investigator/ Principal Investigator	Dr Bevin Bhoyrul
Associate Investigator(s)	
Location	Level 3, 2 Wellington Parade East Melbourne, VIC 3002

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 Sinclair Dermatology.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

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.

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.