Participant Information Statement

Rigenera Protocol Study Patients

Research Study: A Randomised Controlled Trial Assessing the Efficacy of Intra-operative Rigenera Therapy in FUT Hair Transplant Patients

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1. Introduction
We're conducting a research study on the additional use of a stem cell technology called Rigenera in FUT hair transplant and the effect on clinical outcomes. Taking part is optional. Please read this sheet and ask about things that aren't clear or you want to know more on. This Participant Information Sheet and Consent Form tells you about the research project. It explains the purpose of the research, procedures and risks involved. It also describes information about you that will be obtained, how that information will be used and with whom it will be shared. 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 your 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 Form.

2. Who are the investigators?
The researchers conducting this study are:
Dr Adam Ellerby (FRACGP, MBChB, BSc)
Dr Russell Knudsen (MBBS(Hons), FACCSM (Med), FISHRS, Diplomate ABHRS)
Dr Sarah Macdonald (MBBS, Mast. Philosophy, FRACGP)

Dr Adam Ellerby is running this study as part of their Specialty Fellowship with The International Society of Hair Restoration Surgeons (ISHRS). Dr Russell Knudsen is the study supervisor and registered trainer of Dr Ellerby.
This study is funded by The Knudsen Clinic, Sydney.
Conflict of interest declaration - Rigenera equipment and hardware is supplied, without charge by the Austramedex Pty Ltd (92 Abbott Rd, Hallam VIC 3803) of this technology.

There are no financial benefits to the researchers or institutions that will arise from conducting this research.

3. What is the purpose of the study?
This study has been designed to assess the benefit of a newer technology known as Rigenera Autologous Micrograft Therapy (AMT) in hair restoration. We are assessing if there

is any improvement in FUT (Follicular Unit Transplant, aka “Strip surgery”) hair transplant surgery outcomes when performed with Rigenera AMT during the operation.

4. Who can take part in the study?
We are seeking patients with androgenic alopecia who are planning to undergo FUT hair restoration surgery. You must be on hair-loss stabilising medications and aged over 25 years.
You have been invited to participate in this study because you meet this selection criteria. You do not qualify too take part if you have autoimmune or scarring causes of hair loss, underlying systemic disease (chronic infection, diabetes, cancer or similar). If you are unsure please check with the study staff.

5. What will the study involve for me?
If you decide to participate in this study, you will be treated with Rigenera on one side of the scalp and a similar placebo treatment on the other as part of your usual FUT procedure.

During the FUT procedure, some tissue from the strip will be set aside. Using a special kit, this will be processed to create a concentrated solution of your own (“autologous”) stem cells.
These stem cells will then be injected into the area where the new grafts are implanted at the front of the scalp but only on one side. We will assess the effect on hair survival, density and thickness.
The opposite side of the scalp will undergo a placebo version of this process where saline will be injected in a similar fashion to assess if Rigenera has any benefit over placebo. Participants will not be informed which side has received which treatment in order not to skew any results.
The placebo side will not be at any disadvantage as the injection of saline will not negatively affect the outcome nor the success of the surgery.
These processes will be undertaken during the normal operation time and so there is no added time implications to participants on the day of surgery.

Post-operatively participants will be recalled for ongoing assessment. This will include satisfaction surveys on outcomes as well as taking further measurements at 2 weeks, 3, 6 and 12 months after the operation. These reviews are expected to take around 45 minutes each and include taking photographs.

6. Are there any risks or costs?
The current evidence for Rigenera and other stem cell therapies show it to be safe with no recorded adverse outcomes. Injecting of saline in the placebo group will not cause any undue harm, risk or reduction in surgical benefits.
Should you become unwell as a result of any part of this procedure, you must contact The Knudsen Clinic immediately to inform the clinical lead. If there is a rapid deterioration or emergency call 000.
The cost of your FUT procedure however is payable by you. There is no additional cost to you as a participant in the study.
Aside from giving up your time, we do not expect that there will be any risks or costs associated with participating in this study.

7. Are there any benefits?
If the Rigenera technology is effective, this may increase transplanted hair survival, density and thickness and may improve participant satisfaction with their outcome.
The benefit of taking part will help in advancing the hair restoration field for future patients.

8. What is the alternative to taking part?
Taking part in this study is entirely optional. You can decide not to take part in the study, in which case you can undergo the FUT procedure without Rigenera AMT / Placebo treatments. Your decision to take part will not affect your current or future care at The Knudsen Clinic.

9. What happens with tissue collected?
The FUT procedure involves the excision of tissue from the back of the scalp. For this reason tissue collection is obligatory as without it our procedure cannot be performed. Excess tissue from this strip is used to produce the Rigenera solution, so no additional tissue will be taken. Again, the use of tissue is essential to producing the Rignera AMT solution and so collection is obligatory. If you decide not to provide tissue then this will exclude you from the trial.
No tissue other than that described above is collected and none of the collected tissues are stored or processed in any additional ways.

10. Can I withdraw once I've started?
Participating in this study is optional and you do not have to take part.
Your decision will have no impact on your current or future relationship with the researchers or anyone else at The Knudsen Clinic.
If you decide to participate in the study and then change your mind you can withdraw by written request. If you decide to withdraw, we will stop collecting information from you. Any information that we have already collected will be kept in our study records and may still be included in the study results

11. What will happen to information that is collected?
Your records relating to this study and any other information received will be kept strictly confidential and stored securely onsite at The Knudsen Clinic. However, staff participating in your care and other agencies authorised by law, may inspect the records related to the study. In the event you are admitted to hospital as a result of an adverse event resulting from this study, your treating doctor may require access to your study records. Your usual treating Doctor/s may be notified of your participation in this study and of any clinically relevant information noted by the trial doctor, if deemed necessary, during the conduct of the trial.
By giving your consent, you agree to us gathering information about you/from you for this study.
Photographs of the scalp will be taken on the day of surgery and at each follow up. A specialist camera will also be used to take magnified photos of the transplanted area for statistical processing.
Once all follow up has been completed, data will be analysed and published in the medical literature. All data including photographs will be anonymised and participants will not be identifiable.

We plan to publish the findings of this study in the medical literature. You will not be identifiable in these publications.
No third parties will have access to this data unless we are legally obliged.

13. What if I become unwell or have a negative reaction?
As in point 6, there is predicted to be no added risk posed by using Rigenera AMT or placebo during your procedure.
If however you notice any negative reaction you must contact the Knudsen Clinic immediately. We will advise on the best and safest management. In the event you feel very unwell or notice a rapid progression of negative symptoms you should present immediately to your nearest Emergency Department or ring 000. Be sure to keep details of the Knudsen Clinic handy to share with treating medical staff.

14. Is there any compensation for adverse events?
If, as a result of your participation in this study, you become ill or are injured, immediately advise your study doctor of your condition. In the first instance your study doctor will evaluate your condition and then discuss treatment with both you and your regular treating doctor.
Since you are participating in a non-sponsored study/investigation any question about compensation must initially be directed to your study doctor who should advise their insurer of the matter. It is the recommendation of the independent ethics committee responsible for the review of this study/investigation that you seek independent legal advice.

15. Will the study be terminated early?
This research project may be stopped for a variety of reasons. These may include the following:
• Unacceptable side effects,
• the treatment is shown not to be effective,
• the treatment is shown to work and not need further investigation
In this instance the treating doctor will discuss any further follow up outside of the study

16. What if new information arises during the study period?
During the research project, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information. Although highly unlikely, this new information may mean that you can no longer participate in this research. If this occurs, the person(s) supervising the research will stop your participation. In all cases, you will be offered all available care to suit your needs and medical condition.

17. How do I consent?
As well as this information sheet, you will be provided a written consent form to sign. It is important you have read through all the information thoroughly and asked any further questions you may have. You may wish to consider discussing the provided information with a third party such as a friend, family member or your usual GP.

18. Will I be told the results of the study?

You have the right to hear the results of this study. If you wish to be informed of this study's results please inform The Knudsen Clinic in writing. Your individual allocation side selection and data will not be available for review.

19. What if I would like further information?
After reading this information, the researchers will be available to have further discussions with you and answer any questions you may have:
Dr Russell Knudsen
02 9327 0300

20. What if I have a complaint or any concerns?
The ethical aspects of this study have been approved by the Human Research Ethics Committee (HREC) of Belberry [INSERT HREC Approval No. once obtained] in accordance with the National Statement on Ethical Conduct in Human Research (2023).

If you have any concerns about the study's procedures or would like to make a complaint to someone not involved in the study, please contact the Director of HREC Operations, Bellberry Limited on 08 8361 3222

This information is for you to keep.