**Participant Information Sheet/Consent Form**

**Interventional Study**

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| Title | Intraoperative intravenous tranexamic acid during laparoscopic surgery for severe endometriosis – a double-blinded randomised placebo controlled trial |
| Short Title | Tranexamic Acid for severe endometriosis surgery |
| Principal Investigator | Dr Charlotte Reddington |
| Associate Investigators | A/Prof Martin Healey, Dr Claudia Cheng, Dr Uri Dior, Dr Andrew Buettner |
| Location | The Royal Women’s Hospital |

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

**1 Introduction**

You are invited to take part in this research project. This is because you are having surgery for severe endometriosis. The research project is testing a medication to reduce bleeding during endometriosis surgery. The medication is called Tranexamic acid. It is already being used in other surgery such as heart, hip and knee surgery to reduce bleeding.

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 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 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 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?**

Tranexamic acid is a medication that can help reduce bleeding by stopping the breakdown of blood clots. It has been shown to reduce bleeding from many types of surgeries (such as heart, knee, hip, trauma and some gynaecological surgeries). When it has been used to reduce bleeding in surgery, tranexamic acid has not caused an increase in bad outcomes (adverse events). No one has yet done a study to see if tranexamic acid also helps to reduce bleeding in keyhole surgery for severe endometriosis. If less bleeding occurs using tranexamic acid during these surgeries it may also help to make operations shorter and less likely to have complications.

Tranexamic Acid is approved in Australia to reduce blood loss in heart surgery, knee and hip surgery, for people with bleeding disorders having minor surgeries and for people with heavy periods. However it is not approved to reduce bleeding in surgery for endometriosis. Therefore, it is an experimental treatment for reducing bleeding in surgery for endometriosis. This means that it must be tested to see if it is an effective treatment for reducing bleeding in surgery for endometriosis.

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

You will be participating in a randomised controlled research project. Sometimes we do not know if a treatment helps. To find out we need to compare the treatment to a placebo. A placebo is a medication with no active ingredients. It looks like the real thing but is not.

We put people into groups and give each group either the treatment or the placebo. The results are compared to see if the treatment is better than the placebo. To try to make sure the groups are the same, each participant is put into a group by chance (random). In this study you have a one in two chance of receiving tranexamic acid and a one in two chance of receiving the placebo medication.

You will be participating in a double-blind study. This means that neither you nor your study doctor will know which treatment you are receiving. However, in certain circumstances your study doctor can find out which treatment you are receiving.

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 additional costs associated with participating in this research project, nor will you be paid. All medication, tests and medical care required as part of the research project will be provided to you free of charge.

In this study you will be allocated a treatment (which will either be the tranexamic acid OR the placebo). This will be given to you intravenously (into a vein) at the start of your surgery through the same cannula/drip you will receive medication for your anaesthetic medications. While you are asleep under the anaesthetic we will also take a blood test at the start and the end of your surgery. This helps with one method to measure how much blood you have lost during the surgery. If you do not want to have these blood tests taken you can still be part of the study but choose not to have the blood tests. We can still measure your blood loss by weighing and estimation methods. Being a part of this study does not change your surgery or other care in any way.

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

You need to tell us if you have or have had any of the following: a blood clotting disorder, a current or previous blood clot, a subarachnoid haemorrhage (bleed into the brain), treatment for a cancer or blood thinning treatment. If so, you may not be suitable to take part in this study.

To participate in this study you need to

* Complete the consent form at the end of this document

If you are part of this study there are no other restrictions or precautions you need to take. Your surgery and care will not be changed in any way. You can still take all of your usual medication and your recovery from surgery will not be affected.

You are advised to attend a routine post-operative visit after your surgery and tell us about any complications you may have experienced.

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

We plan to recruit 200 participants to this study (100 will receive tranexamic acid and 100 will receive placebo). All participants will be having keyhole surgery for severe endometriosis at the Royal Women’s Hospital.

**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 The Royal Women’s Hospital.

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

There will be no clear benefit to you from your participation in this research. The answers we get from this study will help us to know if tranexamic acid does help to reduce bleeding in surgery for severe endometriosis and this may help many patients in the future.

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

Tranexamic acid used as a one off dose in surgery (like in this study) is very unlikely to cause significant or serious side effects. The side effects listed below are much more likely when tranexamic acid is being used in repeated doses. Some of the possible side effects listed below are also possible risks of having surgery and or a general anaesthetic, whether or not tranexamic acid is given.

You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study 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, your study doctor may need to stop your treatment. Your study doctor will discuss the best way of managing any side effects with you. The following table outlines possible side effects. Please note that:

1. All of the listed side effects can occur as a result of anaesthesia and surgery, regardless of use of Tranexamic Acid.
2. Previous data is from other fields of medicine such as heart surgery which is usually performed on people with underlying medical problems and in which much higher doses were used. Even in those surgeries the risk of serious side effects is “extremely rare” (i.e. a risk of 1/1000-1/10000). We predict in patients undergoing endometriosis surgery this risk would be even lower.

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| --- | --- | --- | --- |
| **Possible Side Effect** | **How often is it likely to occur because of the medication?** | **How severe might it be?** | **How long might it last?** |
| Nausea | Unlikely | Mild - moderate | 1-2 days |
| Blood clots (venous thromboembolism) eg in leg or lung | Extremely rare | Can be serious | Treatment may be required for 6 months or more |
| Eye disorders – change in colour vision or visual impairment | Extremely rare | Moderate - severe | Returns to normal after medication ceased |
| Heart disorders – chest pain or heart attack | Extremely rare | Can be serious | Risk only increased while receiving medication |
| Seizure/convulsion | Extremely rare | Can be serious | While receiving medication only |

Should you experience any side effect related to your participation in this study the Royal Women’s Hospital will provide necessary treatment or referral for necessary treatment.

Having blood taken may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated.

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

Having blood tests while you are asleep under the anaesthetic is an optional part of the study. These will be used to run a Haematocrit level, which is a marker of how dilute or concentrated your blood is. This helps us to measure how much blood you have lost during your surgery. These blood samples will not be stored. Please note these blood tests do not replace the possible need for other blood tests as part of your usual surgical care.

**10 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 study 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 study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests 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.

**11 Can I have other treatments during this research project?**

Yes. Taking part in this study does not change which other treatments you can receive.

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

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

**13 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

• The drug being shown not to be effective

• The drug being shown to work and not need further testing

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

We plan to share the results of this study in relevant scientific journals and conferences. If you would like to receive a summary of the results when the project is completed please indicate this on the consent form. Please note that it will likely take us more than 2 years to complete the study and the results may not be available for another 1-2 years after that.

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

**15 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. You will be allocated a study number and your information will be de-identified. All information will be kept secure: all paperwork from the project will be kept in a locked room and all computerised information will be kept in a database that is password protected. All information will be kept for a period of 7 years after the project is completed, at which time hard copy records will be shredded and computer files deleted.

In any publication, information will be provided in such a way that you cannot be identified. This will be ensured by providing summarised data or else by referring to individual results by their study number. At no stage will a person’s name or any identifying information be provided.

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.

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 study team accessing health records if they are relevant to your participation in this research project.

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.

Information about your participation in this research project may be recorded in your health records.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. 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.

Any information obtained for the purpose of this research project 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.

**16 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.

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

This research project is being conducted by the Gynaecology 2 Unit of the Royal Women’s Hospital. Dr Charlotte Reddington is the principal researcher for the study. We plan to apply for grants from independent bodies to help fund the research.

**18 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 HREC of the Royal Women’s 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.

**19 Further information and who to contact**

If you require further information you may contact the principal researcher, Dr Charlotte Reddington (telephone 03 8345 2000 or email Charlotte.Reddington@thewomens.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: the Royal Women’s Hospital Consumer Advocate, telephone 8345 2290.

**Form for Withdrawal of Participation**

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| --- | --- |
| Title | Intraoperative intravenous tranexamic acid during laparoscopic surgery for severe endometriosis – a double-blinded randomised placebo controlled trial |
| Principal Investigator | Dr Charlotte Reddington |
| Associate Investigators | A/Prof Martin Healey, Dr Claudia Cheng, Dr Uri Dior, Dr Andrew Buettner |
| Location | The Royal Women’s Hospital |

**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 the Royal Women’s Hospital.

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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 |  |  |
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† 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.

**Consent Form**

|  |  |
| --- | --- |
| Title | Intraoperative intravenous tranexamic acid during laparoscopic surgery for severe endometriosis – a double-blinded randomised placebo controlled trial |
| Principal Investigator | Dr Charlotte Reddington |
| Associate Investigators | A/Prof Martin Healey, Dr Claudia Cheng, Dr Uri Dior, Dr Andrew Buettner |
| Location | The Royal Women’s Hospital |

**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 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 consent to the blood samples taken from me for use, as described in the relevant section of the Participant Information Sheet for this specific research project
* I would like a copy of the result in plain English at the completion of the study

(please tick the box if you would like a copy of the result sent to you)

**Declaration by Participant – for participants who have read the information**

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| Name of Participant (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Declaration - for participants unable to read the information and consent form**

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| Witness to the informed consent processName (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 |  |  |
|  |

† 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.