**Participant Information Sheet/Consent Form**

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

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| --- | --- |
| **Title** | Safety, tolerability and pharmacokinetics of 2g subcutaneous ceftriaxone as an alternative to intravenous delivery. |
| **Coordinating Principal Investigator/ Principal Investigator** | A/Prof Laurens Manning |
| **Associate Investigators** | Dr Henco Nel, Dr Fionnuala Murray, Prof Sam Salman, Dr Edward Raby, Matthew Rawlins, and A/Prof Brioni Moore. |
| **Location**  | Fiona Stanley Hospital  |

**1 Introduction**

You are invited to take part in a clinical study which seeks to see if antibiotics delivered subcutaneously (under the skin) is safe, tolerable and as effective as intravenous (into the vein).

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 this research project.

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?**

Ceftriaxone is an antibiotic commonly used for treatment of serious bacterial infections. You have been prescribed this antibiotic by your treating team here in hospital. This antibiotic is currently delivered intravenously - injected into a vein through an intravenous cannula or “drip’. This antibiotic is available in a number of doses up to 2g. This antibiotic can also be given subcutaneously (injected under the skin) with previous studies showing that this is safe and effective. We currently administer the doses up to and including 1g via subcutaneous infusion to patients in the outpatient setting who require prolonged antibiotics when it is difficult or impractical to maintain intravenous access.

The purpose of this study is to assess whether giving the higher 2g dose subcutaneously is well tolerated and to look at plasma concentrations (pharmacokinetics) of ceftriaxone when given subcutaneously, to understand how much of the drug gets into the blood stream, and how quickly the body processes it when delivered that way.

This will help to understand whether giving the higher dose subcutaneously may become an option for patients who need it.

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

**Antibiotic injected subcutaneously (SC)**

If you consent to participate in the study, it will involve one of your doses of antibiotic being given subcutaneously (SC), rather than intravenously (IV).

This involves a nurse or doctor inserting a small, fine needle just under the skin of the abdomen and infusing the antibiotic over 30 minutes. This technique has been used for a number of other antibiotics including a lower dose of ceftriaxone, and studies show that patients often prefer subcutaneous to intravenous injection. After that single subcutaneous dose, your next doses will again be given intravenously as per usual treatment.

**Blood Samples**

This study will involve the collection of a small sample of blood from a finger-prick sample 12 to 13 times in total.

If you are receiving your antibiotic twice daily, a blood sample will be taken before the first dose of antibiotic, and then approximately 1 hour, 3 hours, 5 hours, 8 hours and 12 hours after that dose.

If you are receiving your antibiotic once daily, an additional blood sample will be collected at 24 hours.

**Health and Medical Information**

We would also like to collect information about you to include in the study analysis. Information we will collect includes: your age, weight, height, ethnicity, a full medications list, other health conditions and other blood test results. These will be collected from your patient record in the hospital’s computer system.

In addition, after the SC antibiotics, we will ask you questions about your experience such as how much pain you have at the injection site. We will check the injection sites for any redness, swelling and bruising.

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

**4 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.

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 health service. If you choose not to participate, you will receive regular clinical care and treatment as prescribed.

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

It is unlikely that this study will be of direct benefit to you. However, by participating in this study, you’ll help us find out if the subcutaneous route of antibiotic treatment is a good alternative to intravenous. This may benefit patients like you in the future when intravenous access is difficult or impractical.

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

**Risks associated with SC antibiotic treatment**

There is a small potential risk of skin necrosis (dying tissue) around the site of the subcutaneous injection site. This is very rare. In previous studies of antibiotics administered subcutaneously including ceftriaxone, only 5 cases of skin necrosis were recorded for a total of 10,000 SC injections. Skin necrosis is associated with repeated injection at the same site and is reduced by rotation of the site every 72-96 hours. In this study, you will receive just one dose of antibiotic via the subcutaneous route and therefore this risk is mitigated. The risk is further reduced by the method of preparation of the antibiotic (diluted in normal saline) and equipment used (non-rigid SC catheter).

**Risks associated with taking blood samples**

There are also minor risks associated with having blood samples taken. All blood samples will be collected by finger prick which may cause pain, bruising, bleeding or very rarely infection. Precautions will be taken to ensure the area is sterile before taking the blood samples.

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

Your blood samples will be stored for analysis. Initially this will be in the Harry Perkins Institute of Medical Research Building at Fiona Stanley Hospital.

Once all participants have been recruited we will then send these sample to Curtin University, where the antibiotics levels will be measured.

All information generated will be treated with respect, stored securely and held in strict confidence. Other than a non-traceable study code, we will not collect any identifiable data on you. Blood and other samples will be tagged using a study code that will not be linked to other personal information.

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

Whilst you are participating in this research project, all other treatments will be in accordance with the treatment plan agreed by your attending doctors.

**9 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.

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 your personal information and blood samples already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law.

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

When the research project ends, you will be provided with a summary of the results by your preferred choice, either email or post. This will be approximately mid to late 2025.

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

By signing the consent form, you consent to the study team 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.

Paper records, such as consent forms and case reporting forms, will be stored in a locked office in the Harry Perkins Research Institute of Medical Research, only accessible by the study team. Password protected de-identified electronic data collected will be stored for a period of at least 15 years, accessible only to the study team.

Your information will be used for the purpose of this research project and future research projects looking at this method of delivery and it will only be disclosed with your permission, except as required by law.

The dried blood samples (DBS) will initially be stored in University of Western Australia (UWA) owned freezers at the Harry Perkins Institute of Medical Research before being transferred to Curtin University for sample processing and analysis.

The results of the tests performed at the Curtin University (i.e. antibiotic levels in your blood samples) will also be retained by Curtin in a de-identified format for 15 years. This information will be linked to a unique study code only and will not be re-identifiable. This information may be used for future research projects by Curtin University looking at this method of antibiotic delivery.

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 presented in a variety of forums. In any publication or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

In accordance with relevant Western Australian privacy law 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.

**12 Complaints and compensation**

We do not anticipate any complications of the study, as we expect the SC treatments to be well tolerated. 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

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

This research project is being conducted by A/Prof Manning and members of the Fiona Stanley Hospital Infectious Diseases team. The costs required to measure the antibiotic levels at Curtin University will be covered in-kind by A/Prof Manning and A/Prof Moore.

If knowledge acquired through this research leads to new discoveries, neither the hospital nor study doctors will benefit financially. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages). Furthermore, you will not benefit financially from your involvement in this research project even if, for example, your samples are of benefit for the study.

**14 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 South Metropolitan Health Service HREC.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2023)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

Approved by: South Metropolitan Health Service Human Research Ethics Committee,

smhs.hrec@health.wa.gov.au; Reference number (PRN): RGS00000006590

**15 Further information and who to contact**

The person you may need to contact will depend on the nature of your query.

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 A/Prof Laurens Manning via Fiona Stanley Hospital Helpdesk on 08 6152 2222 (ask to be put through to mobile phone) or any of the following people:

**Clinical contact person**

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| --- | --- |
| Name | A/Prof Laurens Manning |
| Position | Infectious Diseases Physician |
| Telephone | 0400783194 |
| Email | Laurens.manning@health.wa.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 | South Metropolitan Health Service Research Support & Development Unit |
| Position | Manager |
| Telephone | 08 6152 3214 |
| Email | smhs.rgo@health.wa.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 approving this research** **and HREC Executive Officer details**

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| --- | --- |
| Reviewing HREC name | South Metropolitan Health Service  |
| HREC Executive Officer | Ethics Coordinator |
| Telephone | 08 6152 2064 |
| Email | smhs.hrec@health.wa.gov.au |

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

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| --- | --- |
| Name | South Metropolitan Health Service Research Support & Development Unit |
| Position | Research Governance Coordinator |
| Telephone | 08 6152 2646 |
| Email | smhs.rgo@health.wa.gov.au |

**Participant Consent Form**

|  |  |
| --- | --- |
| **Title** | Safety, tolerability and pharmacokinetics of 2g subcutaneous ceftriaxone as an alternative to intravenous delivery. |
| **Coordinating Principal Investigator/Principal Investigator** | A/Prof Laurens Manning |
| **Associate Investigators** | Dr Henco Nel, Dr Fionnuala Murray, Prof Sam Salman, Dr Edward Raby, Matthew Rawlins, A/Prof Brioni Moore. |
| **Location**  | Fiona Stanley Hospital  |

**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 Participant Information Sheet.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the study team 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 understand that, if I decide to withdraw from participation in the above research project, that my withdrawal will not affect my routine treatment or relationship with those treating me or my relationship with Fiona Stanley Hospital. 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.

I consent to the storage and use of blood samples taken from me for use, as described in the relevant section (Section 7) of the Participant Information Sheet, for:

• This specific research project YES / NO

• Other research that is closely related to this research project 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 |  |  |
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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 |  |  |
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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.

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

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| --- | --- |
| **Title** | Safety, tolerability and pharmacokinetics of 2g subcutaneous ceftriaxone as an alternative to intravenous delivery. |
| **Coordinating Principal Investigator/ Principal Investigator** | A/Prof Laurens Manning |
| **Associate Investigators** | Dr Henco Nel, Dr Fionnuala Murray, Dr Sam Salman, Dr Edward Raby, Matthew Rawlins, Brioni Moore |
| **Location**  | Fiona Stanley 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 Fiona Stanley 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 |  |  |
|  |

† 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.