**Participant Information Sheet**

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| **Title** | Efficacy and safety of intra-articular botulinum  toxin A injections in knee osteoarthritis: a randomised control trial |
| **Short Title** | Intra-articular botulinum toxin A in knee osteoarthritis |
| **Coordinating Principal Investigator** | Dr Stephanie Babic |
| **Associate Investigator(s)** | Dr Arnout Faveere  Mr William Blakeney  Mr James Plant |
| **Location** | Royal Perth Hospital |

**1 Introduction**

You are being invited to participate in a research project because you have knee osteoarthritis and you are attending Royal Perth Hospital for treatment of this condition. This Participant Information Sheet explains what will be involved should you decide to participate. Participation in this research is entirely voluntary. You will receive the best care whether or not you choose to participate. Please read the information carefully and ask any questions you might have. You may also wish to discuss the project with your GP, a relative or a friend. You will be given a copy of the Participant Information Sheet and Consent Form to keep.

If you decide you would like to participate in this research, you will be asked to sign the consent section to show that you:

* Understand what you have read;
* Consent to take part in the research project;
* Consent to the treatment options described; and
* Consent to the use of your personal and health information as described.

1. What is the purpose of this research?

The aim of this research is to investigate the effectiveness and safety of knee joint injections with botulinum toxin A (a medication commonly known as ‘Botox’) compared with knee joint injections with normal saline (“salty water”) which is being used in a control group and has no effect on pain.

The use of corticosteroid knee joint injections in knee osteoarthritis has been common in Australia. However, there is emerging research evidence suggesting this may lead to more rapid progression of arthritis. An alternative, Botox injections, may also be a good treatment option for knee osteoarthritis. The evidence so far is promising but limited and so the main aim of this project is to conduct an Australian trial to see if Botox injections are effective at relieving pain and improving function in knee osteoarthritis. **Botox is not currently approved for use as a knee joint injection for osteoarthritis.** Therefore, it is an experimental treatment for knee osteoarthritis and this means it must be tested to see if it is effective.

1. What happens in this trial?

If you agree to participate in this trial we will ask you for some basic information including your age, past medical history, weight, height and what pain medications you take. We will also have 3 questionnaires for you to complete regarding your knee pain and how it impacts on your life. These will be the same questions that you answer for us on a regular basis after your injection. Once you have signed the consent form we will book you for your injection which will either occur on a Monday or Wednesday at Royal Perth Hospital Radiology appointment. You will be contacted by the Radiology department with a time.

1. How does the injection work?

booked for an injection in to your arthritic knee. The injection will be done by a Consultant Musculoskeletal Radiologist with specialist training in doing injections using ultrasound guidance. Using a random number generator you will be allocated to either receive a botox injection or the normal saline injection. You will not be told which injection you will receive and no-one else will know except for the Radiologist.

1. What happens after?

After your injection you will go home and we will mail you the 3 questionnaires you completed before your injection to the address you have provided to the hospital. Please make sure that this is updated with the receptionists at the Royal Perth Orthopaedic clinic before you have your injection. We will be asking you to complete the questionnaires after your injections at the following time periods:

* 2 weeks post injection
* 6 weeks post injection
* 3 months post injection
* 6 months post injection
* 12 months post injection

If you experience any side effects from the medication or are concerned at all please contact the trial email (ktoxtrial@gmail.com) or contact the Royal Perth Orthopaedic Outpatient Clinic and we will arrange for you to be seen in our clinic. Serious adverse events (SAEs) will be reported to the ethics committee and monitored by an independent data monitoring and safety committee.

1. What are the possible Botox side effects?

Because the injection is specifically into the knee joint the risk of side effects is low. Potential side effects include bruising or pain at the injection site, muscle weakness, a heart arrhythmia, dysphagia (difficulty swallowing), anaphylaxis OR allergic reaction and a skin rash at the injection site.

The potential side effects of injecting normal saline into the knee joint are extremely low. The main potential side effect would be bruising or pain at the injection site.

1. Cost of Participation

There is no cost to you to participate in this research project. You will not be paid for participating. All medication, tests and medical care required as part of the research project will be provided to you free of charge.

1. Voluntary participation and withdrawal

Participation in any research project is entirely 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 will not affect your routine treatment, your relationship with those treating you or your relationship with *Royal Perth Hospital*.

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

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 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.

1. Possible benefits of participation

Participation in this project may have no direct benefit for you but may help with better management of knee osteoarthritis for the Australian community in the future. If you receive the placebo injection we do not expect you to have any improvement in symptoms. If you receive the botox injection the possible benefits include a decrease in pain and/or improvement in your knee function.

1. Privacy and Confidentiality

The information gathered about you by the investigator or obtained during this project will be held by the investigator in strict confidence as far as the law allows. All the people who handle your information will comply with the *Privacy Act 1988* (Cth). Your study data will be held securely at *Royal Perth Hospital*. Where the data is electronic, it will be held on secure servers in a ‘re-identifiable’ format. This means the research data is ‘coded’ with your data held against a unique study code, not your name. Once the data for the whole study is complete, the code link that matches your name and study code will be deleted meaning it will be impossible from that point forward to match you to your data (i.e. the research data will be ‘non-identifiable’).

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 the *Privacy Act 1988* (Cth) and other relevant Australian 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.

1. Complaints and Compensation

In the event that you suffer an expected or unexpected side effect or medical accident during this project that arises from your participation, you will be offered all full and necessary treatment by Royal Perth Hospital. Participation in this project does not alter any right to compensation that you may have under statute or common law.

**Contacts for further information**

**Clinical contact**

If you have questions about this project, or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), please contact the study doctor Dr Arnout Faveere or Dr Stephanie Babic through the RPH Switchboard or Department of Orthopaedics Research Assistant. Alternatively for non-urgent matters you can email the research team

**HREC**

This project has been granted ethical approval by the Royal Perth Hospital (RPH) Human Research Ethics Committee (HREC). If you have any concerns about the conduct of the project or your rights as a research participant, phone (08) 9224 2292 or email: EMHS.REG@health.wa.gov.au and quote the ethics approval number RGS0000004752.

**Consent Form**

|  |  |
| --- | --- |
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| **Coordinating Principal Investigator** | Dr Stephanie Babic |
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| **Location** | Royal Perth Hospital |

I have read the Participant Information Sheet and 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 this hospital to release information to Royal Perth Hospital concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential as far as the law allows.

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.

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|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
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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.

Form for Withdrawal of Participation

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| --- | --- |
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| **Location** | Royal Perth 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 Royal Perth. I understand that data collected up until the time of withdrawal will continue to be used in the study.

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|  | | | | | | |
|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
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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.

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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.