

**TITLE OF PROJECT:** Intra-articular injection of platelet-rich plasma in patients with knee osteoarthritis. A randomised controlled trial.

**PRINCIPAL INVESTIGATOR/SUPERVISOR:** Dr Kade Paterson

**Co-INVESTIGATOR:** Dr Dan Bates

**STUDENT RESEARCHER:** Miss Melissa Nicholls

**COURSE:** Bachelor of Exercise and Sports Science (Honours)


Dear participant,

Thank you for considering participation in this study that aims to investigate the effect of platelet-rich plasma (PRP) injections for treatment of knee osteoarthritis (OA) on pain and activity. The study is being conducted by a student researcher in collaboration with Dr Dan Bates from Lakeside Sports Medicine Centre and under the supervision of Dr Kade Paterson.

If you decide to participate, you will be required to attend Lakeside Sports Medicine Centre for six visits of approximately 45 minutes each, at times suitable to you. The study will initially require a full assessment of your affected knee to determine study eligibility and may require you to have further X-rays or scans as is commonplace with an initial medical consultation for knee OA. If you choose to participate, you will be required to cease any pain or anti-inflammatory medications (except Paracetamol) for three weeks prior to the first injection. You will also be randomly assigned to one of two groups to receive either the PRP injection or an injection of a widely used medication for osteoarthritis (Synvisc®). The PRP injected into your joint is a concentrated platelet solution that is prepared immediately at the clinic from 20 millimetres of your own blood. Recent evidence suggests that PRP is an emerging treatment option that may reduce pain and improve physical function in people with knee OA. Synvisc® is a synthetic solution that is similar to the fluid normally found in joints and is a treatment that has been used safely for more than 10 years to assist with lubrication and shock absorption, and thus may reduce symptoms of pain. To remove bias, neither yourself, the treating doctor or the researchers will know which solution you will receive.

Prior to your initial treatment visit, you will first be required to complete three online surveys that are self reported questions on symptoms such as pain and activity restrictions, to evaluate the severity of your osteoarthritis symptoms. During this visit you will complete two functional tests to assess the muscular strength and ability of both legs by performing simple movements that are similar to everyday activities. The first functional assessment will require you to complete three trials on each leg, of a single hop for maximal distance, whilst the second test will require you to perform as many shallow knee bends as possible for 30 seconds.

After these assessments, you will then receive the first of three treatment injections. Twenty milliliters (a tablespoon) of blood will be collected from a vein on the inside of your arm. The blood collected will be taken to an adjacent laboratory and processed for approximately 20 minutes to obtain the platelet-rich plasma portion. Following this, either five milliliters of PRP solution obtained from your blood, or



two milliliters of Synvisc® will be injected into your knee joint by Dr Bates with the use of an ultrasound machine to accurately direct the injection to the affected area.

You will then be required to return to the clinic weekly for another two injections resulting in a total of three treatment injections with either PRP or Synvisc®. Following your third injection, pain and activity restrictions association with your knee osteoarthritis will be recorded daily for the first two weeks, then weekly for the next two weeks. Additionally, four and eight weeks after the final injection, you will be required to return to the clinic to repeat the three surveys and two functional tests performed on your first treatment visit. You will also be contacted weekly via phone to monitor your progress and record any issues arising from the treatment.

No significant side effects from the study treatment are to be expected, however, all studies carry some possible risks, discomfort and inconvenience to participants. The potential risks to participants in this project include discomfort or infection associated with injection of solution into the knee joint however all procedures will employ standard sterile medical techniques to minimize potential side effects. There is also a small risk of discomfort, a fainting spell or bruising associated with blood collection. To minimize stress or discomfort an explanation of procedures will be given to you prior to treatment.


It is possible that you will gain some benefit from participating in this study. It is hoped that the treatment with PRP will result in a reduction in pain and stiffness, thus encouraging increased activity levels and an improvement in muscular strength surrounding the affected joint. There may be potential benefits to society in general as more information is collected regarding osteoarthritis, thus contributing to a greater understanding of future treatment options for OA.

As a participant in this study, it is important that you understand that you are free to refuse consent to participate altogether without having to justify that decision. You are also able to withdraw consent and discontinue participation in the study at any time without giving a reason and without affecting your future treatment, or your relationship with Lakeside Sports Medicine Centre and those treating you.

All data collected will be treated confidentially by the researchers and individual data will only be known to the researchers. It is anticipated that the results of this study will be published with only group data reported, however a coding system will be used to maintain confidentiality. As such, you will not be able to be identified from your data in any way.

Any questions regarding this project, or any issues raised in this information letter, may be directed to the Principal Investigator:

Dr Kade Paterson  
School of Exercise Science  
115 Victoria Parade  
Fitzroy VIC 3065  
Tel: +613 9953 3031



Any data will be made available upon request by contacting the Principal Investigator so that you may have a better understanding of the project and its outcomes.

This study has been approved by the Human Research Ethics Committee at Australian Catholic University, and independent advice or any complaints should be directed to:

Chair, HREC  
C/- Research Services  
Australian Catholic University  
Melbourne Campus  
Locked Bag 4115  
FITZROY VIC 3065  
Tel: 03 9953 3158  
Fax: 03 9953 3315

Any complaint made will be treated in confidence, investigated fully and the participant informed of the outcome.

If you agree to participate in this project, you should sign both copies of the Informed Consent form, retain one copy for your records and return the other copy to the researchers to be filed by the supervisor at ACU, Fitzroy Campus, in a securely locked filing cabinet.

Thank you for your cooperation with this important research.

Yours sincerely,

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