<To be printed on local headed paper>

Achilles Tendinopathy Management

PATIENT INFORMATION SHEET

We would like to invite you to take part in our research study, investigating the benefit of a new type of treatment for Achilles tendon pain.

Before you decide whether to take part we would like you to understand why the research is being done and what it would involve for you. A researcher from our team will go through this information sheet with you and answer any questions you have.

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KEY CONTACTS

- <insert trust PI or research team> XXXX XXX XXXX
- Dr Rebecca Kearney: [redacted]
  (Chief Investigator at University of Warwick)
- Coordinating centre, University of Warwick Clinical Trials Unit: ATM@warwick.ac.uk
- Patient Advice Liaison Service (PALS): XXXX XXX XXXX

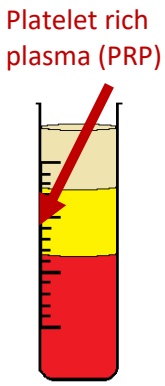
1. Background information

You have been diagnosed with Achilles tendon pain (Achilles tendinopathy) that has persisted for more than 3 months. Achilles tendinopathy is routinely managed with advice and painkillers. If initial management fails there are a range of other treatments available, but no single treatment has been proven to be effective.

2. What is the purpose of this study?

The purpose of the study is to look into whether a new injection treatment is beneficial to patients with Achilles tendon pain. An Arthritis Research UK group has identified this new type of injection as being potentially helpful. We would like to look into this further with your help. The study is funded by Arthritis Research UK and is coordinated by University of Warwick Clinical Trials Unit. Dr Rebecca Kearney is the overall lead for this study.

This new treatment involves taking a small sample of your blood, mixed with anticoagulant, to stop the blood clotting, which is then spun in a machine to separate out the components of the blood. The part of the blood we are interested in is the plasma containing a high number of platelets, known as platelet rich plasma (see diagram of blood split into its components within a tube).



Platelets play an important role in the repair processes within tendons. The clinical trial plans to test whether platelet rich plasma (PRP) injection help with painful Achilles tendons. By injecting the PRP into the painful tendon, you may experience increased healing and reduced pain.

If you participate in the study, you will be asked to provide information about your pain, ability to perform activities, complications and overall health. The study is important as we want to see whether this treatment is the best for future patients with Achilles tendon pain so that they will receive the best possible treatment.

3. Why have I been chosen?

You have been chosen because you have had Achilles tendon pain for more than 3 months. There will be other hospitals in England taking part in the study and 240 patients will take part in total.

4. Do I have to take part?

It is up to you whether or not to take part. If you decide to take part you will be given this information sheet and asked to take as much time as is required to consider your decision. If you decide to proceed you will sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time or a decision not to take part will not affect the standard of care you receive.

5. Which treatment will I receive?

You will be allocated to either the platelet rich plasma (PRP) injection or the placebo (imitation) injection. The allocation process will be done by a computer and is done purely by chance. There is an equal chance of you receiving either the PRP injection or the placebo (imitation) injection. We need to have a placebo injection in order to clearly see whether the PRP injection treatment is the best to use for future patients with Achilles tendon pain. You will not be told which treatment you are allocated to. Six months after treatment, when you receive your six month follow up questionnaire, you will be asked if you would like to know the allocation you received. If you indicate that you would, then the trial team will contact you to let you know..

6. What will happen if I take part?

Day 1: Questionnaires and injection treatment

You will be asked to complete a questionnaire (baseline questionnaires) about your pain, activity and current health. You will not be told which treatment you will be allocated but your clinician will know and allocate the treatment. A small amount of blood will be taken from a vein in your arm in order to prepare a sample of PRP. If a vein is difficult to find, blood may be taken from your hand or foot. You will be asked to lie face down on a clinic bed on the day of the treatment. Local anaesthetic applied near your Achilles tendon. The blood taken from you will be spun very fast to separate the PRP from the other blood components. Your injection treatment will then be administered on the same day.

INJECTIONS	
Platelet Rich Plasma (PRP)	*Placebo (imitation)*
If you are allocated to receive the PRP injection treatment, your PRP sample will be injected into the Achilles tendon.	If you are allocated to receive the placebo (imitation) injection, a needle will be inserted under the skin near to your Achilles tendon. No blood or PRP will be injected into this area, the process is done to simulate the injection process only.

You will receive a care and information sheet following the injection procedure. You will receive a standard recovery programme by your clinician and asked not to do any other treatments for six months. This makes sure everyone in the study receives similar treatment after the injection.

Post-injection treatment schedule of events:

2 weeks:

You will receive a telephone appointment from the University of Warwick two weeks after the receipt of the injection treatment so that we can review the injected tendon. This will only take 5-10min of your time.

3 months: Postal *Questionnaires only.*

You will receive a questionnaires in the post (with a free post return envelope) asking about

your current pain, activity and current health so we may have an update on your condition. This will only take 10min of your time.

6 months: Postal *Questionnaires only*

You will be asked to complete questionnaires asking for another follow up on your current pain, activity and health. This will be sent in the post with a free post return envelope. This will only take 10min of your time.

With your permission, we may occasionally phone or send you a mobile text message to inform you that questionnaires are due. We will ask you for your name, address, telephone numbers and a next of kin contact. Next of kin details will be used in the event that we are unable to contact you through the contact details provided. It is really important that we receive your completed questionnaires as the answers you provide will give us an indication of how effective the treatment you have been given is to reduce pain and heal the tendon. Your NHS number will be also recorded. This information will be sent to, stored and used by the University of Warwick Clinical Trials Unit to enable us to follow up on your condition whilst you are participating in the study. All information will be treated with the strictest security and confidentiality (see section ***13. Will my taking part in this study be kept confidential?*** for further information on confidentiality).

7. What are the possible disadvantages and risks of taking part?

There are no specific risks of receiving PRP because it is created using your own blood. However disadvantages of receiving any injection include soreness, bruising and swelling at the injection sites (where your blood was taken and around the Achilles tendon), this is a common effect. There is also a very low risk of infection, but this is no greater than when receiving any injection. We are not aware of any risks over and above those when receiving any injection.

8. What are the possible benefits of taking part?

We do not know whether this new treatment will give the best results therefore there may be no immediate benefit to you for taking part. You may receive the PRP injection which may aid or speed up your healing. The PRP is not routinely available in the NHS so may not be available as a treatment outside of this study. There are no known risks to receiving PRP . The information that you provide us with by taking part in the trial may inform us about future treatments.

9. What if new information becomes available?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, a researcher from Warwick Clinical Trials Unit will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, we will encourage you to discuss your continued care with your doctor. If you decide to continue in the study you will be asked to sign an updated consent form.

10. What happens when the research study ends?

You will be in the study for 6 months. If you are still having problems after this time, your clinician will arrange for you to have an appointment with an appropriate specialist to continue your care.

11. What happens if there is a problem?

In the unlikely event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Warwick. This study is covered by the University of Warwick's insurance and indemnity cover. If you have an issue, please contact the Chief Investigator of the study: ATM@warwick.ac.uk.

12. Who should I contact if I wish to make a complaint?

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a Senior University of Warwick Official, entirely independent of this study:

Address: Director of Delivery Assurance, Registrar's Office, University House, University of Warwick, Coventry, CV4 7AL, Email: Complaints@Warwick.ac.uk, Telephone: 02476 574 774

13. Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves Warwick Clinical Trials Unit will have your name and address removed so that you cannot be recognised from it. Your GP will be notified of your participation in the study, with your consent.

14. What will happen to the results of the research study?

The study is expected to take place until February 2019. Once all of the data has been gathered, we will publish the findings in medical journals and at medical conferences. You will not be identified in any reports or publications resulting from the study. If you would like to know the final results of the study we will ask you to indicate this on your 6 month follow up questionnaire. If you do, we will post you a lay summary of the study results, once the study is complete..

15. What will happen if I decide not to participate in the research study?

If you decide not to participate in the research study your care will not be affected and you will be followed up in the usual way. You are free to withdraw consent from the trial at any time.

16. Who has reviewed this study?

This study has been reviewed by the *West Midlands –Black Country Research Ethics Committee.*

17. Contacts for further information

If, at any time, you would like further information about this research project you may contact your clinician, telephone number xxxx xxx xxx <Trust to insert contacts here>

You may also contact the ATM office for further information: ATM@warwick.ac.uk. For independent advice contact the PALS service (Patient Advice Liaison Service) on XXXX XX XXX

THANK YOU FOR CONSIDERING PARTICIPATION IN THIS STUDY AND FOR TAKING TIME TO READ THIS INFORMATION SHEET