Achilles Tendinopathy Management – Analysis of PRP

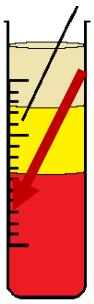
PARTICIPANT INFORMATION SHEET

You are invited to take part in a research project. 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.

1. What is the purpose of this study?

The ATM study is a UK wide study testing if a new treatment for Achilles pain works. The treatment involves taking a small sample of the patients' 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 (PRP) (see diagram of blood split into its components within a tube). The PRP is then injected into the painful tendon.

Platelet rich plasma (PRP)



The aim of this study is to test the quality of the PRP sample that is created using the same method and counting the number of cells present. The PRP sample will be compared against a blood sample that has not been spun in a machine or altered in any way. The samples will be sent to a laboratory for analysis.

2. Why have I been chosen?

You have been chosen because you are not known to have any illnesses and we would like to collect two samples of your blood approx. 10ml each. One will be used as a whole blood sample and one blood sample will be used for the creation of the PRP sample.

3. Do I have to take part?

It is up to you whether or not to take part. We will ask you to read this patient information sheet and to take as much time as is required to consider your decision. If you decide to proceed we will invite you to University Hospital Coventry and Warwickshire (UHCW) at a date and time to suit you. When you arrive you will sign a consent form and then we will proceed with taking up to two blood samples of 10 ml each. If you decide to take part you are still free to withdraw at any time and without giving a reason.

4. What will happen if I take part?

If you decide to take part you will have a telephone screening phone call to check you are eligible and you will asked to sign a consent form when you arrive at UHCW. A trained member of the team will take a small amount of blood from a vein in your arm in order to prepare two samples of blood, one sample of whole blood (approximately 10ml), which will remain as it is and the other blood sample (approximately 10ml) will be processed as a PRP sample in the method outlined above. If a vein is difficult to find, blood may be taken from your hand or foot. This should take no more than 30 minutes. Once we have taken the samples, you will not need to contribute any further samples or time. The blood samples will then be sent to a laboratory in Birmingham, United Kingdom for analysis. The samples will be anonymised and destroyed following analysis.

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

Disadvantages of blood being taken may include soreness, bruising and swelling at the sites where your blood was taken, this is a common effect. There is also a very low risk of infection.

6. What are the possible benefits of taking part?

There are no specific benefits to taking part. To recompense your time and cost of travel, we will give you a voucher for £50.

7. 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.

8. 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

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

Any information about you which leaves the University of Warwick will have your name removed so that you cannot be recognised from it. The blood samples will remain anonymous and will be destroyed once they have been analysed following standard laboratory procedures.

10. What will happen to the results of the research study? (can we delete this?)

The results from this study will contribute to the ATM study where we will publish the findings in medical journals and at medical conferences. You will not be identified in any reports or publications.

11. Who has reviewed this study?

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

12. Contacts for further information

If you would like to take part please 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