UK Study of tendo Achilles Rehabilitation

Chief Investigator: Professor Matt Costa

PATIENT INFORMATION SHEET

We would like to invite you to take part in a research study investigating two different types of rehabilitation. Before you decide to participate in the study we would like you to understand why the research is being done and what it would involve for you. Someone from our team will go through the information sheet with you and answer any questions you have.

What is the purpose of this study?

Your Achilles tendon connects your calf muscle to your heel bone. The tendon is extremely important for walking, running and standing on tiptoes. Your Achilles tendon can tear (rupture) without warning. When you tear your Achilles tendon you may experience sudden pain, as if you have been kicked on the back of the leg. Tearing your Achilles tendon is a serious and debilitating injury and recovery takes several months. During the early stages of healing the tendon, the treatment is based around providing support and protection.

There are different ways to achieve this and the purpose of this study is to compare two different methods of rehabilitation to find out which is best for patients who have torn their Achilles Tendon.

Why have I been invited?

You have torn your Achilles tendon. This has made you eligible to be part of this research project.

We expect that over 20 hospitals across the country will be taking part in this study and we hope to recruit a minimum of 330 patients with a similar injury to yours.

Do I have to take part?

No, it is entirely your decision whether you choose to take part or not. Throughout the study 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. However, we will not be able to remove the data we have already collected prior to your decision to withdraw.

What will happen if I decide to take part?

If you decide you would like to be involved in the research study you will be asked to sign a consent form. You will then be allocated to either receive a Plaster cast or a Walking boot. The treatment you receive will be allocated using a computer. You have the same chance to be entered in the plaster cast group as in the walking boot group.

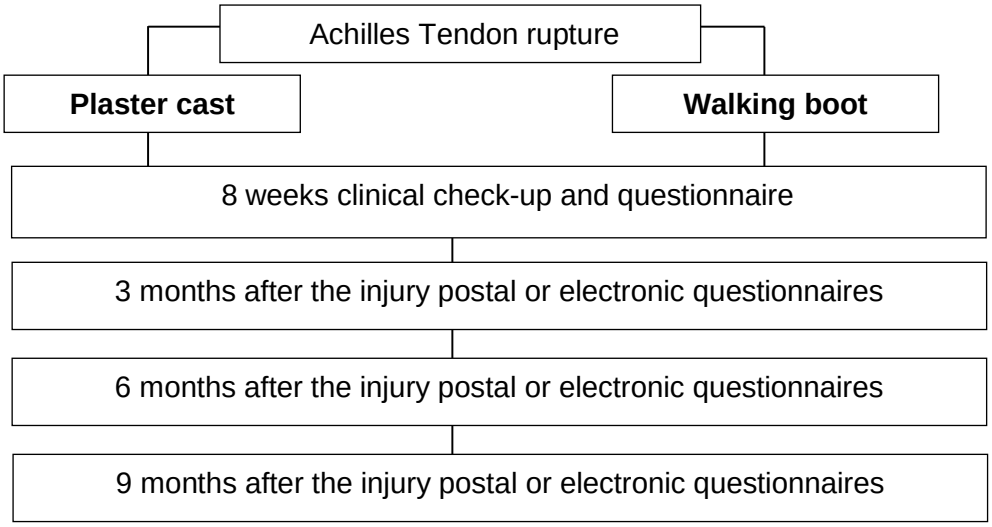
You will be followed-up according to the usual treatment at your hospital, in the same way as patients not taking part in this study. The only additional commitment we would ask of you would be to fill out a questionnaire on four occasions during your recovery.

After signing the consent form, we will ask you to fill out the first questionnaire. The questionnaire will ask you about how well you were able to perform certain day-to-day tasks and how you were feeling before your injury occurred. The questionnaire will take approximately 10 minutes to complete.

The UKSTAR trial is funded by the National Institute for Health Research's HTA Programme.

When you leave the hospital, your doctor will arrange to see you at regular intervals for routine check-ups. We will follow how your recovery progresses over the next 9 months. We propose to do this in two ways. Firstly the research team will obtain relevant information from your hospital records and central UK NHS records to see how you are getting on. This will include information about how long you spent in hospital, what treatments you required and how well you recovered. Secondly the research team will ask you to fill out a questionnaire at 8 weeks, 3, 6 and 9 months after your injury. The questions will be very similar to those asked at the start of the study. The questionnaire will either be sent to you in the post or electronically by email or text message as you prefer. If we send it out in the post, we will provide you with a stamped-addressed envelope to send it back to us once you have filled it out.

The flow-chart below shows a schedule of the activities/assessments and what would happen after the injury.



We will occasionally send you a mobile text message to inform you a questionnaire is due. We may also contact you or your alternative contact if we have not received your questionnaire and to check that we hold your current address.

What is the difference between the rehabilitation methods?
The two different rehabilitation methods are a 'plaster cast' and a 'walking boot'.

Plaster cast
The plaster cast is applied below your knee. At first, the cast will hold your leg in a position where your toes will point down towards the floor. This is so that the ends of the torn tendon are close together as they heal. You will get crutches and can use your toes for balance, but you won't be able to put your full weight on this leg. As your tendon starts to heal the position of the plaster cast is changed so that your foot becomes flat to the floor and you can start to walk. The cast will be removed at around 8 weeks. The plaster cast provides maximum protection for your healing tendon. In particular, it restricts the upward movement of the ankle which may stretch the healing tendon. However, it does not allow you to put weight on your foot immediately.

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Walking boot

The walking boot is also fitted below your knee. Inside the boot, there are small wedges which sit under your heel. The wedges lift up your heel and bring the ends of the healing tendon closer together. You will still need crutches to help you balance but the boot will allow you to put weight on your foot. As your tendon starts to heal, the wedges will be removed so that your foot becomes flat to the floor and you can walk without the crutches. The boot will be removed at 8 weeks.

The walking boot does not provide the same support as the plaster cast. In particular, it allows more movement of the healing tendon.

After 8 weeks

When the cast/boot is removed after 8 weeks, we will provide you with written advice about the exercises you need to perform to strengthen your calf muscles and support the healing tendon. The advice has been put together for research trials into Achilles Tendon Rupture, with the help of a large group of physiotherapists and doctors around the country. The advice is the same for patients with the walking boot and the plaster cast.

What are the possible disadvantages and risks of taking part?

There are no specific risks of having one type of rehabilitation method or the other. The risks of the injury are the same for both groups of patients in the study, and are the same as for patients who are not taking part in the study.

What are the possible benefits of taking part?

Both rehabilitation methods are used across the NHS for patients with a torn Achilles tendon so there is no specific advantage to you for taking part in the study. However, the information we get from this study will help us to improve treatment for future patients with similar injuries. It will also provide valuable information on the best use of resources within the NHS.

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, the research team 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.

What happens if something goes wrong?

The University of Oxford is the Sponsor for the study and has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this trial. If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Professor Matt Costa who is the overall lead of this trial on xxxxx xxxxxx or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on xxxxx xxxxxx or the head of CTRG, email ctrg@admin.ox.ac.uk.

NHS indemnity covers any other treatment with which you are provided.

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Will my taking part in this study be kept confidential?

A copy of your consent form and paperwork will also be held by the STAR trial team at the University of Oxford. Only appropriate personnel will have access to your record and all information will be treated with the strictest security and confidentiality.

All information which is collected about you during the course of the research will be kept strictly confidential. Your personal details will be held by the research team at the University of Oxford but these will not be released to anyone not involved in the study. With your consent, your GP and other staff who may treat you but are not part of this study, will be notified that you are taking part. When the results of the study are reported or published, individuals who have taken part will not be identified in any way.

What will happen to the results of the research study?

This research study is expected to last 3 years. We will publish the findings of the study at the end of the study in medical journals and at medical conferences. We will also let you know about the results of the study.

Who has reviewed this study?

This study has been reviewed by the *South Central Oxford B Research Ethics Committee* and approval was given on 18th of March 2016. This study is supported by a grant from the National Institute for Health Research.

Contacts for further information

If, at any time, you would like further information about this research project you may contact the Trial Manager of this research study by telephoning xxxxx xxxxxx. Or you can contact your local research lead <<insert name of local researcher>> telephone number <<insert telephone number>> or Professor Matthew Costa, who is the overall lead of this study on xxxxx xxxxxx.

The PALS service is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS can give general advice, however they will not be able to give specific information regarding this study.

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