ISRCTN68273773 https://doi.org/10.1186/ISRCTN68273773

# Study of Tendo Achilles Rehabilitation

**Submission date**
22/08/2013

**Recruitment status**
No longer recruiting

**Registration date**
22/08/2013

**Overall study status**
Completed

**Last Edited**
15/04/2015

**Condition category**
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Rupture of the Achilles tendon (that attaches calf to the heel bone) is a serious and disabling injury. The condition can cause prolonged periods off work and away from sporting activity for much longer. Extended hospital stay and delayed healing have significant financial and health impact for the patient, the NHS and society as a whole. Therefore, it is important to find the best way to treat patients with this injury in order to get them back to their normal activity as quickly as possible. This study aims to find out the best treatment for an Achilles tendon rupture. We are comparing two treatments  one involves a walking boot and one involves a plaster cast, both are standard existing treatments.

Who can participate?
All patients coming with an acute Achilles tendon rupture will be invited to take part in this initial study. A total of 20 patients will be recruited.

What does the study involve?
All patients will be randomly allocated to either the walking boot group or the plaster cast group. The allocation process will be done by a computer and will be done purely by chance. All patients will be asked to fill out a questionnaire about their health and activities. These same questions will be asked on three occasions during the recovery process. The results we get from one treatment group will then be compared with the results we get from the other group.

What are the possible benefits and risks of participating?
This research will inform a UK-wide study to ensure that all patients receive the best treatment in the future. We do not know which of these treatments gives the best results; both treatments are already available and used widely within the NHS.

Where is the study run from?
Warwick Clinical Trials Unit at the University of Warwick, UK.

When is study starting and how long is it expected to run for?
The study will start in November 2013 and is expected to run for two years.

Who is funding the study?
National Institute for Health Research (NIHR), UK.

Who is the main contact?
Dr Rebecca Kearney
r.s.kearney@warwick.ac.uk

# Contact information

### Type(s)
Scientific

### Contact name
Dr Rebecca Kearney

### Contact details
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX
-
r.s.kearney@warwick.ac.uk

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
14105

# Study information

### Scientific Title
Accelerated rehabilitation for patients with a rupture of the Achilles tendon: A mixed-methods approach to evaluating clinical outcomes and cost-effectiveness

### Acronym
STAR

### Study objectives
Eleven thousand patients sustain a torn Achilles tendon each year, yet our knowledge of rehabilitation following this injury is limited. This pilot project will investigate two different methods of rehabilitation: accelerated rehabilitation using a functional bracing protocol versus standard treatment in plaster cast.
To achieve this a national survey of doctors will be undertaken to find out about what current practice is. To design this survey a focus group consisting of approximately ten doctors will be consulted. This will be followed by inviting approximately twelve doctors who have responded to the survey to take part in an interview to gain feedback on their experience of this injury. This

will be followed by inviting and interviewing ten patients who present to the University Hospitals of Coventry and Warwickshire with a torn Achilles tendon rupture, to inform the design of a pilot trial comparing the two treatments.

More details can be found here: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=14105

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
12/WM/0083

## Study design
Randomised; Interventional; Design type: Not specified, Treatment

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied
Topic: Musculoskeletal; Subtopic: Musculoskeletal (all Subtopics); Disease: Musculoskeletal

## Interventions
1. Plaster cast immobilisation: One treatment group will receive a plaster cast placed in a planter-flexed position, for a duration of eight weeks. During this period patients will be told not to bear weight until the final two weeks.
2. Walking Boot: One treatment group will receive a walking boot, in which the foot will be placed in a plantar-flexed position, for a duration of eight weeks. During this period patients will be told to weight bear immediately and remove the walking boot for short periods during the day to perform ankle range of movement exercises.

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome measure

Achilles tendon Total Rupture Score - This is a patient reported outcome score containing ten items, for which patients are asked to respond using an 11 point Likert scale to measure the construct of `symptoms and physical activity'.

### Secondary outcome measures
1. EQ-5D - A validated, generalised, quality of life questionnaire consisting of 5 domains related to daily activities with a 5-level answer possibility. The combination of answers leads to the QoL score.
2. SF12 - The Short-Form 12 is a validated and widely-used health-related quality of life measure
3. Complications - all complications will be recorded
4. Resource use will be monitored for the economic analysis.

### Overall study start date
01/04/2013

### Completion date
31/12/2015

## Eligibility

### Key inclusion criteria
1. All patients over 18 years presenting at either the University Hospitals of Coventry and Warwickshire with a primary acute rupture of their Achilles tendon (within 10 days of rupture) would be eligible to take part.
Target Gender: Male & Female ; Lower Age Limit 18 years

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
Planned Sample Size: 30; UK Sample Size: 30

### Key exclusion criteria
1. Patients presenting after 14 days from injury or with a history of previous Achilles tendon rupture would be excluded.
2. Patients who had other serious injuries to either lower limb that would alter the intervention and subsequent rehabilitation would also be excluded. This is in addition to patients who are unable to adhere to trial procedures, with explicit reasons documented and reported.

### Date of first enrolment
01/04/2013

**Date of final enrolment**
31/12/2015

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**University Hospital, Coventry**
Coventry
United Kingdom
CV2 2DX

# Sponsor information

**Organisation**
University of Warwick (UK)

**Sponsor details**
University House
Kirby Corner Road
Coventry
England
United Kingdom
CV4 8DS

**Sponsor type**
University/education

**ROR**
https://ror.org/01a77tt86

# Funder(s)

**Funder type**
Government

**Funder Name**
NIHR Trainees Coordinating Centre (UK)

# Results and Publications

## Publication and dissemination plan
Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary
Not provided at time of registration

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/04/2015 | | Yes | No |