

Study of Tendo Achilles Rehabilitation

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| Submission date 22/08/2013 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 22/08/2013 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 15/04/2015 | Condition category Musculoskeletal Diseases | <input type="checkbox"/> 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
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Contact information

Type(s)
Scientific

Contact name
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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 |