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UK Study of tendo Achilles Rehabilitation

Submission date	Recruitment status	[X] Prospectively registered
09/06/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
22/06/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/07/2023	Injury, Occupational Diseases, Poisoning	

Plain English summary of protocol

Current plain English summary as of 01/08/2018:
Background and study aims
The Achilles tendon is the largest tendon in the human body and transmits the powerful contractions of the calf muscles that are required for walking and running. Consequently, when the tendon ruptures it has a serious detrimental impact on daily activities and results in prolonged periods off work and away from sporting activity. Achilles tendon rupture affects over 11,000 people each year in the UK, and the incidence is increasing as the population remains more active into older age. Controversy remains with regards the best rehabilitation plan for patients with a rupture of the Achilles. Traditionally, patients have been treated in a series of plaster casts; the casts extend from below the knee and around the ankle. The position of the cast is changed until the patient can put their weight through the foot. However, there is some evidence that a functional brace or 'walking boot' gives as much support and may speed recovery in the first year after the injury. We therefore propose to perform a study comparing plaster casts with functional bracing for patients with a rupture of the Achilles tendon. Phase 1 will confirm how many patients are willing to take part in a large-scale multi-centre randomised controlled trial. Phase 2 will be the proposed randomised controlled trial in a minimum of 22 hospitals across the UK.

Who can participate?
Adult patients attending a trial centre with a rupture of the Achilles tendon who have decided not to have surgery.

What does the study involve?
Patients will be randomly allocated to be treated with either functional bracing or a plaster cast. Both plaster casts and functional braces are widely used within the NHS, for both broken bones and sprains, and all of the clinical teams in the trial centres will be familiar with both techniques. A researcher will perform a clinical assessment and make a record of any early complications at 8 weeks. Functional outcome, quality of life and questionnaires of out-of-pocket expenses will be collected at 3, 6 and 9 months post-injury.

What are the possible benefits and risks of participating?
There are no specific risks or benefits to participants as both interventions are already used widely in the treatment of patients with an Achilles tendon rupture. The risks of an Achilles tendon rupture include: re-rupture, tendon lengthening, calf muscle weakness and blood clots,

and these risks are present for both groups of patients in the study and indeed all patients with this injury.

Where is the study run from?
Oxford University Hospitals NHS Trust (UK).

When is the study starting and how long is it expected to run for?
April 2016 to May 2019

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK).

Who is the main contact?
Dr Susan Wagland
UKSTAR@ndorms.ox.ac.uk

Previous plain English summary:
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Contact information

Type(s)
Scientific

Contact name
Dr Susan Wagland

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Additional identifiers

Protocol serial number
HTA 13/115/62; v1.0

Study information

Scientific Title
UK Study of tendo Achilles Rehabilitation – a multicentre randomised clinical trial

Acronym
UK STAR

Study objectives
There is no difference in the Achilles Tendon Rupture Score 9 months after rupture of the Achilles tendon, in non-operatively treated adult patients with either functional bracing or plaster cast immobilisation.

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/1311562

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central - Oxford B Research Ethics Committee, 18/03/2016, REC ref: 16/SC/0109

Study design
Multi-centre two-arm parallel-group assessor-blind randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Achilles tendon rupture

Interventions
Participants will be randomized 1:1 to the following two groups:
1. A plaster cast will be applied in the 'gravity equinus' position. Over the first 8 weeks, as the tendon heals, the position of the plaster cast is changed until the foot achieves 'plantargrade'. Weight bearing can commence thereafter.
2. A rigid functional brace will be applied, with equines foot position initially. Weight bearing can commence immediately. Plantargrade will be achieved gradually over 8 weeks after which the brace will be removed.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
-

Primary outcome(s)
The primary outcome measure for this study is the Achilles tendon Total Rupture Score (ATRS). The ATRS is a validated questionnaire which is self-reported (filled out by the patient). It consists of 10 items assessing symptoms and physical activity specifically related to the Achilles tendon. It measures: strength, fatigue, stiffness, pain, activities of daily living, walking on uneven surfaces, walking upstairs or uphill, running, jumping and physical labour. This data will be collected at baseline, 3, 6 and 9 months post-injury.

Key secondary outcome(s))
1. EQ-5D; The EQ-5D-5L is a validated, generic health-related quality of life measure consisting of 5 dimensions each with a 5-level answer possibility.
2. Complications; all complications will be recorded, from the medical records at the 8-week review and self-reported by the patient thereafter, including: re-rupture, blood clots/emboli, pressure areas/hindfoot pain, falls and neurological symptoms in the foot.

Completion date
31/05/2019

Eligibility

Key inclusion criteria
Patients will be considered for participation in this study if:
1. They are aged 16 years or older
2. They have a primary rupture of the Achilles tendon
3. They have decided to have non-operative treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex
All

Total final enrolment
540

Key exclusion criteria
Patients will be excluded from participation in this study if they:
1. Present to the treating hospital more than 14 days after the injury
2. There is evidence that the patient would be unable to adhere to trial procedures or complete questionnaires; for example, a history of permanent cognitive impairment

Date of first enrolment
01/07/2016

Date of final enrolment
31/05/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Oxford University Hospitals NHS Trust
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
University of Oxford (UK)

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Matt Costa (matthew.costa@ndorms.ox.ac.uk).
1. Type of data that will be shared: individually assessed on request for data sharing
2. When the data will become available and for how long: individually assessed on request for data sharing
3. By what access criteria data will be shared including with whom: individually assessed on request for data sharing
4. For what types of analyses: individually assessed on request for data sharing
5. By what mechanism: individually assessed on request for data sharing
6. Whether consent from participants was obtained: no
7. Comments on data anonymization: all data will be de-identified
8. Any ethical or legal restrictions: individually assessed on request for data sharing
9. Any other comments: none

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/02/2020	10/02/2020	Yes	No
Results article		01/02/2020	10/07/2023	Yes	No
Protocol article	protocol	24/10/2017	03/06/2019	Yes	No
HRA research summary			28/06/2023	No	No
Statistical Analysis Plan	statistical analysis plan:	30/05/2019	03/06/2019	No	No