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Post-operative bracing following repair of the Achilles tendon

Submission date 14/10/2021	**Recruitment status** Not yet recruiting	[X] Prospectively registered [X] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 03/11/2021	**Overall study status** Ongoing	
Last Edited 22/10/2021	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims:
An Achilles tendon rupture is a tear of the tendon that connects the calf muscles to the heel bone. Following an Achilles tendon rupture it is routine to protect patients in a cast or a brace to allow them to move around or mobilise. Mobilising is good, encourages the tendon to heal and avoids complications like blood clots in the calf veins. A previous method used a front shell with patients putting weight on the balls of their feet and not loading on the heel area of the foot at all for 6 weeks. Patients managed using this method did well, reporting good outcome scores and functional tasks on assessment. Their tendons did however lengthen slightly and if they had a fall or a stumble, and put too much weight onto the injured leg to stop their fall, could re-rupture their tendons.
Most treatments use a protective brace for at least 8 weeks and many provide support underneath the midfoot and heel such as a boot with wedges. The aim of this study is to compare the outcome of patients following minimally-invasive Achilles tendon repair mobilising for 6 weeks of weight-bearing in an anterior shell with those mobilising for 8 weeks in an anterior shell and heel wedges.

Who can participate?
Patients aged 18-65 years with an acute Achilles tendon rupture who underwent surgery

What does the study involve?
The aim is to study a group of patients who had received a similar repair of their Achilles tendon in terms of suture material and repair technique, but received a longer period of protection for 8 weeks. From 2-8 weeks following repair patients are allowed to mobilise, with the assistance of crutches, in a walker boot with wedges under the midfoot and heel in addition to the anterior cast shell.
Participating in the study involves nothing other than reading the patient information leaflet, agreeing to take part in the study and signing the consent form. The patient's management and evaluation would actually be routine patient management with nothing additional.

What are the possible benefits and risks of participating?
The only benefit in taking part is the knowledge that patients may be contributing to science. There is a theoretical risk of taking part in that tendons might heal tighter but this does not appear to be the case from previous studies, with tendon lengthening being the main problem.

Where is the study run from?
Shrewsbury & Telford Hospital NHS Trust (UK)

When is the study starting and how long is it expected to run for?
May 2021 to May 2028

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Mr Mike Carmont
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Contact information

Type(s)
Scientific

Contact name
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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
295136

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 295136

Study information

Scientific Title
Comparison of methods and duration of post-operative bracing following repair of acute Achilles tendon rupture

Acronym
POBRAT

Study objectives
The aim of this study is to compare the outcome of patients following minimally-invasive Achilles tendon repair mobilising for 6 weeks of weight-bearing in an anterior shell with those mobilising for 8 weeks in an anterior shell and heel wedges.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/04/2021, South Central - Oxford C Research Ethics Committee (Health Research Authority (Bristol), Ground Floor, Temple Quay House, 2 The Square, BS1 6PN, UK; +44 (0)207 104 8379; oxfordc.rec@hra.nhs.uk), REC ref: 07/MRE08/9

Study design
Non-randomized cohort comparison study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

See additional files

Health condition(s) or problem(s) studied
Post-operative bracing following repair of the Achilles tendon

Interventions
Contemporaneous data collection is performed at routine follow up at the completion of brace use at 6 and 8 weeks, and at 3, 6, 9 and 12 months following repair. The primary outcome measure is the Heel-Rise Height Index (HRHI), comparing maximal sustained heel-rise of the injured side to the non-injured side at 12 months following repair. The HRHI is an indirect measure of tendon elongation. Secondary outcome measures include the ATRA, a validated direct measure of tendon length, the Achilles tendon Total Rupture Score (ATRS), a patient-reported outcome measure, the Tegner Score, and the Patient Perception of Performance.

Intervention Type
Procedure/Surgery

Primary outcome measure
Tendon elongation measured using the Heel-Rise Height Index (HRHI), comparing maximal the sustained heel-rise of the injured side to the non-injured side at 12 months following repair

Secondary outcome measures
Measured at 3, 6, 9 and 12 months following repair:
1. Tendon length measured using the Achilles Tendon Resting Angle (ATRA)
2. Symptoms and function measured using the Achilles tendon Total Rupture Score (ATRS)
3. Work and sports activities assessed using the Tegner Score

Overall study start date
26/05/2021

Completion date
31/05/2028

Eligibility

Key inclusion criteria
1. Mid-substance Achilles tendon rupture, diagnosed clinically by the presence of a palpable gap to the Achilles tendon, and increased Achilles Tendon Resting Angle and a calf squeeze test
2. Aged 18-65 years
3. Presenting <15 days following rupture
4. Able to understand the spoken and written English language
5. After consultation wishes to have operative repair of the Achilles tendon rather than non-operative management
6. Available for 12 months follow up at Shrewsbury and Telford Hospital NHS Trust

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
64

Key exclusion criteria
1. Distal Achilles tendon rupture, identified by palpation of the distal stump ending <2 cm proximal to the Achilles insertion
2. Musculotendinous Achilles tendon ruptures, diagnosed by tenderness at the musculotendinous junction and on ultrasonography. Ultrasonography will be used for the confirmation of musculotendinous rupture rather than midsubstance rupture
3. Patients with diabetes mellitus, chronic inflammatory conditions, and musculoskeletal conditions preventing a single heel-rise prior to rupture
4. A previous ipsilateral or contralateral Achilles tendon rupture
5. Patients >110 kg and BMI >30 kg/m² owing to obesity giving an increased risk of wound, cast and functional brace complications

Date of first enrolment
31/05/2027

Date of final enrolment
01/01/2028

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Royal Shrewsbury Hospital
Shrewsbury & Telford Hospital NHS Trust
Mytton Oak Road
Shrewsbury
United Kingdom
SY3 8XQ

Sponsor information

Organisation
Shrewsbury and Telford Hospital NHS Trust

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Sponsor type
Hospital/treatment centre

Website
https://www.sath.nhs.uk/

ROR
https://ror.org/047feaw16

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal and conference presentation.

Intention to publish date
01/01/2029

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Mr Mike Carmont (m.carmont@nhs.net). Data will be anonymised before sharing.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3	27/04/2021	21/10/2021	No	Yes
Protocol file	version 4	28/03/2021	21/10/2021	No	No