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Does using an absorbable or a permanent suture during the repair of Achilles tendon rupture lead to a better outcome?

Submission date
14/06/2021

Recruitment status
No longer recruiting

Registration date
09/08/2021

Overall study status
Ongoing

Last Edited
03/08/2021

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Operative repair of the ruptured Achilles tendon leads to improved ankle plantar flexion strength, less tendon elongation and reduced time to return to work than non-operative management. Minimally invasive repair of the tendon shows similar outcome to operative repair however has reduced risk of complications such as infection and wound breakdown.
Both absorbable and non-absorbable suture materials have been used to repair the Achilles tendon and have resulted in good outcome although differing suture techniques, sizes, type of suture and rehabilitation methods make comparison difficult. The Carmont and Maffulli modified percutaneous repair technique was first described in 2007 and since then has shown good outcome in many patient groups. The original technique used Maxon sutures, an absorbable monofilament suture. Since then Fiberwire and Vicryl braided sutures have been used but patient outcomes have not been directly compared in a single study.
The aim of this study is to compare the functional outcome of patients who had sustained a rupture of the Achilles tendon and had this repaired using a minimally -invasive repair using either absorbable or non-absorbable suture material.

Who can participate?
Patients aged 18 - 65 years with a mid-substance Achilles tendon rupture.

What does the study involve?
Participants will be required to provide written consent to participate. Participants will be allocated at random to one of the two suture materials. Apart from the suture material all other elements of the participant's care and the operation will remain the same. Participants will not be told which suture material will be used until the end of the trial, this is to minimise any bias to the study. Participants can find out which material was used after follow up (12 months) is completed. Follow up visits would be held at the 2, 3, 6, 9, and 12 months following injury. No additional visits would be required unless the participant encountered issues. During the follow-up period score sheets and simple measurements would be performed to determine the tendon and calf muscle function.

What are the possible benefits and risks of participating?
Both suture materials are safe and effective, producing good results. This study is trying to show if one is more effective than another. Both have advantages and disadvantages as already discussed however these may only become apparent when a large group of patients are evaluated. On an individual level a complication simply may or may not occur.
Potential benefits of receiving an absorbable suture include that the suture material will be absorbed over time, so any prominent knot may disappear and over time, without the suture, the tendon may be more springy. Also if the suture becomes infected this will be absorbed and will not need to be removed. Disadvantages of receiving an absorbable suture is that they tendon may be more likely to elongate leading to calf weakness and the absorption process may weaken the tendon making it more likely to re-rupture.
Potential benefits of receiving a non-absorbable suture are that it is stronger and will not weaken with absorption over time, potentially making the tendon less likely to re-rupture. Disadvantages include that as a permanent suture the remodelling tendon may be irritated by the presence of the suture and may thicken losing springiness. Additionally if the suture material becomes colonised by bacteria from infection the suture may have to be removed.

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

When is the study starting and how long is it expected to run for?
September 2020 to January 2027

Who is funding the study?
Shrewsbury and Telford Hospital NHS Trust (UK)

Who is the main contact?
Mr M Carmont, m.carmont@nhs.net

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
288885

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 288885

Study information

Scientific Title
Minimally-Invasive Achilles Suture Trial (MIAST): Non-Absorbable vs. Absorbable

Acronym
MIAST

Study objectives
The aim of this study is to compare the functional outcome of patients who had sustained a rupture of the Achilles tendon and had this repaired using a minimally -invasive repair using either absorbable or non-absorbable suture material.
The null hypothesis is that there would be no difference in the plantar flexion strength at one year following repair.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/01/2021, Wales REC 4 Wrexham (Health and Care Research Wales Support Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)7976 982591; Wales.REC4@wales.nhs.uk), ref: 20/WA/0332

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
treatment of Achilles rupture

Interventions
The aim of this study is to compare the functional outcome of patients who had sustained a rupture of the Achilles tendon and had this repaired using a minimally -invasive repair using either absorbable or non-absorbable suture material.

Participants will be randomised to either receiving a Vicryl or Fiberwire suture. Follow up visits would be held at the 2, 3, 6, 9, and 12 months following injury as per clinical practice - no additional visits would be required unless the participant reported issues. F/U involves score sheets and simple measurements to determine tendon and calf muscle function.

Randomisation to use a computer-generated binary sequence and sealed envelope allocation.

Intervention Type
Procedure/Surgery

Primary outcome measure
Plantar flexion strength determined by 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

Secondary outcome measures
1. Relative Achilles Tendon Resting Angle measured using a goniometer by the technique of Carmont et al. at the 3 and 12 month time point of routine patient follow up evaluation.
2. The Achilles tendon Total Rupture Score questionnaire (ATRS at 12 months)
3. Activity measured using Tegner Score questionnaire at 12 months
4. Patient Perception of Performance measured using patient interview at 12 months
5. Patient’s acceptability of the received suture measured using patient interview at 12 months
6. Occurrence of complications measured using patient's notes and observation during follow up evaluation (12 months)

Overall study start date
03/09/2020

Completion date
11/01/2027

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. Age 18 - 65 years
3. Active patients with Tegner ≥5 (Generally participates in sports on regular basis and is recreationally competitive
4. Presenting <15 days following rupture
5. Able to understand the spoken and written English language
6. After consultation wishes to have operative repair of the Achilles tendon rather than non-operative management.
7. Available for 12 months follow up at SATH

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 <2cm proximal to the Achilles insertion
2. Musculotendinous Achilles tendon ruptures
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 & BMI >30 kg/m² owing to obesity giving an increased risk of wound, cast and functional brace complications

Date of first enrolment
15/01/2021

Date of final enrolment
15/01/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Shrewsbury and Telford Hospital NHS Trust
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/047feaw16

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
Shrewsbury and Telford Hospital NHS Trust

Results and Publications

Publication and dissemination plan
peer reviewed journal, trust website

Intention to publish date
01/01/2028

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2		03/08/2021	No	Yes
Protocol file	version 4	12/12/2020	03/08/2021	No	No
HRA research summary			28/06/2023	No	No