ISRCTN13254422 https://doi.org/10.1186/ISRCTN13254422

Achilles tendon pain management (ATM): A study to evaluate an injection to improve pain in the Achilles tendon

Submission date
28/10/2015

Recruitment status
No longer recruiting

Registration date
28/10/2015

Overall study status
Completed

Last Edited
08/11/2023

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Current plain English summary as of 04/06/2019:
Background and study aims
Every year more than 150,000 people suffer from pain at the back of the heel, leading to walking difficulties. The most common cause of this is Achilles tendinopathy, also known as Achilles tendonitis. Achilles tendinopathy is a condition where the Achilles tendon becomes damaged, causing pain, swelling and stiffness. The Achilles tendon is a very strong band of tissue which connects the calf muscle to the heel bone. There are two main areas that are affected, the middle of the tendon (mid-substance Achilles tendinopathy) and where the tendon meets the heel bone (insertional Achilles tendinopathy). Mid-substance Achilles tendinopathy is thought to happen when the tendon is unable to repair itself after it has been injured. Currently, the main treatments for Achilles tendinopathy involve a combination of self-help techniques, physical therapy, medications and even surgery, although the most effective treatment is widely debated. Platelet-rich plasma (PRP) is a part of the blood plasma (the liquid part of the blood) with a high platelet concentration. Platelets are blood components which play an important role in the healing process. The aim of this study is to find out whether injections of PRP can help speed up healing and reduce pain in patients with mid-substance Achilles tendinopathy.

Who can participate?
People aged 18 years or over, who have been suffering from painful Achilles tendons for more than three months.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group have a blood sample taken, which is spun in a machine to separate out the components of the blood. The PRP is then injected into the skin near the painful tendon. Participants in the second group are given a placebo (imitation) injection into the painful tendon. At the start of the study and then again after two weeks, three and six months, participants in both groups complete questionnaires in order to find out whether there has been any change to their pain levels and ability to perform activities.

What are the possible benefits and risks of participating?
Participants may benefit from reduced pain due to the PRP injection. The risks of participating are minor, however, participants may experience pain, swelling or bleeding, skin discolouration and possible allergic reaction to the PRP injection.

Where is the study run from?
NHS hospitals in England (UK)

When is the study starting and how long is it expected to run for?
June 2016 to September 2020

Who is funding the study?
Arthritis Research UK (UK), now known as “Versus Arthritis”

Who is the main contact?
1. Jaclyn Brown (Public)
2. Dr Rebecca Kearney (Scientific)

Previous plain English summary as of 29/04/2019:
Background and study aims
Every year more than 150,000 people suffer from pain at the back of the heel, leading to walking difficulties. The most common cause of this is Achilles tendinopathy, also known as Achilles tendonitis. Achilles tendinopathy is a condition where the Achilles tendon becomes damaged, causing pain, swelling and stiffness. The Achilles tendon is a very strong band of tissue which connects the calf muscle to the heel bone. There are two main areas that are affected, the middle of the tendon (mid-substance Achilles tendinopathy) and where the tendon meets the heel bone (insertional Achilles tendinopathy). Mid-substance Achilles tendinopathy is thought to happen when the tendon is unable to repair itself after it has been injured. Currently, the main treatments for Achilles tendinopathy involve a combination of self-help techniques, physical therapy, medications and even surgery, although the most effective treatment is widely debated. Platelet-rich plasma (PRP) is a part of the blood plasma (the liquid part of the blood) with a high platelet concentration. Platelets are blood components which play an important role in the healing process. The aim of this study is to find out whether injections of PRP can help speed up healing and reduce pain in patients with mid-substance Achilles tendinopathy.

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June 2016 to August 2020

Who is funding the study?
Arthritis Research UK (UK), now known as “Versus Arthritis”

Who is the main contact?
1. Mariana Bernardo (Public)
2. Dr Rebecca Kearney (Scientific)

Previous plain English summary as of 30/11/2018:
Background and study aims
Every year more than 150,000 people suffer from pain at the back of the heel, leading to walking difficulties. The most common cause of this is Achilles tendinopathy, also known as Achilles tendonitis. Achilles tendinopathy is a condition where the Achilles tendon becomes damaged, causing pain, swelling and stiffness. The Achilles tendon is a very strong band of tissue which connects the calf muscle to the heel bone. There are two main areas that are affected, the middle of the tendon (mid-substance Achilles tendinopathy) and where the tendon meets the heel bone (insertional Achilles tendinopathy). Mid-substance Achilles tendinopathy is thought to happen when the tendon is unable to repair itself after it has been injured. Currently, the main treatments for Achilles tendinopathy involve a combination of self-help techniques, physical therapy, medications and even surgery, although the most effective treatment is widely debated. Platelet-rich plasma (PRP) is a part of the blood plasma (the liquid part of the blood) with a high platelet concentration. Platelets are blood components which play an important role in the healing process. The aim of this study is to find out whether injections of PRP can help to speed up healing and reduce pain in patients with mid-substance Achilles tendinopathy.

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NHS hospitals in England (UK)

When is the study starting and how long is it expected to run for?
June 2016 to August 2020

Who is funding the study?
Arthritis Research UK (UK), now known as “Versus Arthritis”

Who is the main contact?
1. Bushra Rahman (Public)
2. Dr Rebecca Kearney (Scientific)

Previous plain English summary:
Background and study aims
Every year more than 150,000 people suffer from pain at the back of the heel, leading to walking difficulties. The most common cause of this is Achilles tendinopathy, also known as Achilles tendonitis. Achilles tendinopathy is a condition where the Achilles tendon becomes damaged, causing pain, swelling and stiffness. The Achilles tendon is a very strong band of tissue which connects the calf muscle to the heel bone. There are two main areas that are affected, the middle of the tendon (mid-substance Achilles tendinopathy) and where the tendon meets the heel bone (insertional Achilles tendinopathy). Mid-substance Achilles tendinopathy is thought to happen when the tendon is unable to repair itself after it has been injured. Currently, the main treatments for Achilles tendinopathy involve a combination of self-help techniques, physical therapy, medications and even surgery, although the most effective treatment is widely debated. Platelet-rich plasma (PRP) is a part of the blood plasma (the liquid part of the blood) with a high platelet concentration. Platelets are blood components which play an important role in the healing process. The aim of this study is to find out whether injections of PRP can help to speed up healing and reduce pain in patients with mid-substance Achilles tendinopathy.

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Where is the study run from?
NHS hospitals in England (UK)

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

Who is funding the study?
Arthritis Research UK (UK)

Who is the main contact?
1. Dr Joanne O'Beirne-Elliman (Public)
2. Dr Rebecca Kearney (Scientific)

Study website
http://www2.warwick.ac.uk/fac/med/research/hscience/ctu/musculoskeletalandpain/atm

Contact information

Type(s)
Public

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Type(s)
Scientific

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Gibbet Hill Road
Coventry
United Kingdom
CV4 7AL

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
187315

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 19870, IRAS 187315

Study information

Scientific Title
Achilles tendinopathy management (ATM): A multi-centre placebo-controlled randomised trial comparing platelet rich plasma (PRP) to placebo injection in adults with Achilles tendon pain

Acronym
ATM

Study objectives
The aim of this study is to investigate whether plasma rich injection (PRP) can help to increase healing and reduce pain in patients with painful Achilles tendons. In adults with painful mid-substance Achilles tendinopathy lasting longer than three months, does a single injection of platelet rich plasma improve VISA A scores by a minimum of 12 points when compared to a placebo injection at six months post injection?

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service Committee – The Black Country, 30/10/2015, ref: 15/WM/0359

Study design
Randomized; Interventional; Design type: Not specified, Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Achilles tendinopathy

Interventions
Participants are randomly allocated to one of two groups:

Control group: Participants receive a placebo injection into the skin near the painful tendon

Intervention group: Participants have a blood sample taken which is then spun in a centrifuge to separate out the blood components and collect platelet rich plasma (PRP). They then receive a PRP injection into the painful tendon

Participants in both groups are followed up at 2 weeks, 3 and 6 months, in which the severity of their Achilles tendinopathy and quality of life is measured.

Intervention Type
Other

Primary outcome measure
Dysfunction of the Achilles tendon (pain, function and activity) is measured using the Victorian institute of sport assessment-Achilles (VISA-A) questionnaire at baseline, 3 months and 6 months.

Secondary outcome measures
1. Health related quality of life is measured using the EQ5D-5L questionnaire at baseline, 3 months and 6 months

Added 19/10/2016:
2. Pain is measured using a visual analogue score (VAS) is assessed at baseline, 2 weeks, 3 and 6 months using a patient questionnaire
3. Complications are recorded at 2 weeks, 3 and 6 months using a patient questionnaire

Overall study start date
01/09/2015

Completion date
29/09/2020

Eligibility

Key inclusion criteria
1. Provision of written informed consent
2. Aged 18 years or over
3. Pain at the mid-substance of the Achilles tendon for longer than 3 months
4. Ultrasound and/or MRI confirmation of tendinopathy

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 240; UK Sample Size: 240; Description: 1:1

Total final enrolment
240

Key exclusion criteria
1. Presence of systemic conditions (including: diabetes, rheumatoid arthritis, peripheral vascular disease)
2. Pregnant or actively trying to become pregnant, or breastfeeding at the time of randomisation
3. Have had prior Achilles tendon surgery or rupture on the index side
4. Previous major tendon or ankle injury or deformity to either lower leg
5. Have had a fracture of a long bone in either lower limb in the previous 6 months
6. Have any contraindication to receiving a platelet rich plasma injection (haemodynamic instability, platelet dysfunction syndrome, cancer, septicaemia, systemic use of anticoagulant, local infection at site of the procedure)
7. Are unable to adhere to trial procedures or complete questionnaires
8. Previous randomisation in the present trial

Added 19/10/2016:
9. Previous PRP treatment into a tendon.

Date of first enrolment
01/06/2016

Date of final enrolment
21/02/2020

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre

University Hospital Coventry
University Hospitals Coventry and Warwickshire
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
Ninewells Hospital and Medical School
NHS Tayside
Dundee
United Kingdom
DD2 1UB

Study participating centre
Norfolk and Norwich University Hospital
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Norwich
United Kingdom
NR4 7UY

Study participating centre
Northern General Hospital
Sheffield Teaching Hospitals NHS Foundation Trust
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
Leicester General Hospital
University Hospitals of Leicester NHR Trust
Gwendolen Road
Leicester
United Kingdom
LE5 4PW

Study participating centre
The Princess Royal Hospital
Shrewsbury and Telford Hospital NHS Trust

Apley Castle
Grainger Drive
Telford
United Kingdom
TF1 6TF

Study participating centre
North Tyneside General Hospital
Northumbria Healthcare NHS Foundation Trust
Rake Lane
Tyne and Wear
North Shields
United Kingdom
NE29 8NH

Study participating centre
Leighton Hospital
Mid Cheshire Hospitals NHS Foundation Trust
Middlewich Road
Crewe
United Kingdom
CW1 4QJ

Study participating centre
Morriston Hospital
Abertawe Bro Morgannwg University Health Board
Heol Maes Eglwys
Morriston
Cwmrhydyceirw
Swansea
United Kingdom
SA6 6NL

Study participating centre
Arrowe Park Hospital
Wirral University Teaching Hospital NHS Foundation Trust
Arrowe Park Road,
Upton
Birkenhead
United Kingdom
CH49 5PE

Study participating centre
Wexham Park Hospital
Frimley Health NHS Foundation Trust
Wexham Street
Slough
United Kingdom
SL2 4HL

Study participating centre
Royal Liverpool Hospital
Royal Liverpool and Broadgreen University Hospitals NHS Trust
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
Robert Jones and Agnes Hunt Orthopaedic Hospital
Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust
Gobowen
Oswestry
United Kingdom
SY10 7AG

Study participating centre
Doncaster Royal infirmary
Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust,
Thorne Road
Doncaster
United Kingdom
DN2 5LT

Study participating centre
Royal Devon and Exeter Hospital
Royal Devon and Exeter NHS Foundation Trust,
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
Musgrove Park Hospital
Taunton and Somerset NHS Foundation Trust,
Parkfield Drive
Taunton
United Kingdom
TA1 5DA

Study participating centre
Prince Charles Hospital
Cwm Taf University Health Board,
Gurnos Road
Merthyr Tydfil
United Kingdom
CF47 9DT

Study participating centre
Basildon Hospital
Basildon and Thurrock University Hospitals NHS Foundation Trust,
Nethermayne
Basildon
United Kingdom
SS16 5NL

Study participating centre
George Eliot Hospital
George Eliot Hospital NHS Trust,
College Street
Nuneaton
United Kingdom
CV10 7DJ

Study participating centre
University Hospital of Hartlepool
North Tees and Hartlepool Hospitals NHS Foundation Trust,
Holdforth Road
Hartlepool
United Kingdom
TS24 9AH

Study participating centre

Llandough Hospital
Cardiff & Vale University Health Board
Penlan Road
Llandough
United Kingdom
CF64 2XX

Study participating centre
Alexandra Hospital
Worcestershire Acute Hospitals NHS Trust,
Woodrow Drive
Redditch
United Kingdom
B98 7UB

Study participating centre
Wharfedale Hospital
Leeds Community Healthcare NHS Trust,
Newall Carr Road
Otley
United Kingdom
LS21 2LY

Study participating centre
St Mary's Hospital
Imperial College Healthcare NHS Foundation Trust,
Praed Street,
Paddington
London
United Kingdom
W2 1NY

Sponsor information

Organisation
University of Warwick

Sponsor details
Clinical Trials Unit
Warwick Medical School
Gibbet Hill Road

Coventry
England
United Kingdom
CV4 7AL

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research UK

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
A summary of the trial outcomes will be disseminated to trial participants on relevant websites and newsletters. A final report to Arthritis Research UK will be produced in addition to publications in peer-reviewed medical journals and presentations at relevant conferences. The results may also contribute to future NICE guidance on the topic of platelet rich plasma injections.

Intention to publish date
31/03/2021

Individual participant data (IPD) sharing plan
The data will be held at Warwick Clinical Trials Unit in accordance with their Standard Operating Procedures on storing and sharing data.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	12/02/2020	14/02/2020	Yes	No
Results article		13/07/2021	14/07/2021	Yes	No
HRA research summary			28/06/2023	No	No
Protocol (other)		13/07/2021	08/11/2023	No	No
Statistical Analysis Plan		13/07/2021	08/11/2023	No	No