

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

<b>Submission date</b> 28/10/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 28/10/2015	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/11/2023	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> 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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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. 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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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)

## Contact information

**Type(s)**  
Public

**Contact name**  
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**Type(s)**  
Scientific

**Contact name**  
Dr Rebecca Kearney

**ORCID ID**  
<https://orcid.org/0000-0002-8010-164X>

**Contact details**  
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Warwick Medical School  
Gibbet Hill Road  
Coventry  
United Kingdom  
CV4 7AL

## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**Integrated Research Application System (IRAS)**  
187315

**Protocol serial number**

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

**Study type(s)**

Treatment

**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(s)**

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.

### **Key secondary outcome(s)**

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

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **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**

United Kingdom

England

Scotland

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**

**Morrison Hospital**

Abertawe Bro Morgannwg University Health Board  
Heol Maes Eglwys  
Morrison  
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

**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

## 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?
<a href="#">Results article</a>		13/07/2021	14/07/2021	Yes	No
<a href="#">Protocol article</a>	protocol	12/02/2020	14/02/2020	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Protocol (other)</a>		13/07/2021	08/11/2023	No	No
<a href="#">Statistical Analysis Plan</a>		13/07/2021	08/11/2023	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes