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High Volume Saline Injections for Achilles Tendinopathy

Submission date	Recruitment status	[ ] Prospectively registered
28/05/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
24/07/2012	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/05/2019	Musculoskeletal Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Achilles tendon disorders (heel cord disorders) are a common problem for athletes with a lifetime risk of around 50%. They are also common for less active people with a lifetime risk of around 6%. Achilles Tendinopathy, caused by overuse of the heel cord, is a condition, causes pain, difficulty with weight bearing and performing usual activities and swelling. There is a well researched physiotherapy (physical therapy) program (called eccentric loading) which is highly effective for heel cord disorder. Most people will have major relief of symptoms if they follow this program. However, there is no clear answer as to what the next best treatment is if physiotherapy fails. This study is testing an injection of saline (salty water) given around the heel cord to alleviate pain and comparing this against an injection of drugs.

Who can participate?
Any adult with heel cord disorder who has ongoing symptoms despite completing a 3 month program of physiotherapy exercises

What does the study Involve?
Participants are randomly allocated to one of two groups: the new treatment group (high volume saline injection + steroid and local anaesthetic) or the active comparator group (just steroid and local anaesthetic injection). Each participant has a stretching exercise regime demonstrated to them and receives an advice booklet on how to recover following the injection. After the injection has been given, the participant returns and outcome measures are again recorded to compare the symptoms in the two groups. The doctor then reveals which injection was received. If the participant still has symptoms at this time and they belong to the comparator group, they are offered the saline injection at this time. All participants are followed up again after another 6 weeks and again 9 months later to see if symptoms are recurring at all.

What are the possible benefits and risks of participating?
Early research has shown a possible relief of symptoms from the saline injection. Participants also have access to high quality rehabilitation advice at their appointments. A helpline number is given to all participants and calls are usually returned within 24 hours. The risk of infection

following soft tissue injections is usually around 1 in 2000. Any participant receiving a second injection would be exposed to this risk a second time. There is a theoretical risk of heel cord rupture, although this has never been reported.

Where is the study run from?
The study is run by the Leeds Musculoskeletal and Rehabilitation Service which is a part of the Leeds Community Healthcare NHS Trust. The administration centre of the study is at Chapel Allerton Hospital in Leeds. Research clinics take place across the city of Leeds, predominantly at Wharfedale Hospital in Otley, north of Leeds.

When is the study starting and how long is it expected to run for?
The study began recruiting patients in March 2012 which will be completed by March 2013. Follow up and data analysis is expected to be completed by March 2014 and publication of results will follow later that year.

Who is funding the study?
The study is financed from Flexibility and Sustainability Funding allocated to Leeds Community Healthcare NHS Trust by the National Institute of Health Research (NIHR) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01583504

Protocol serial number
11/YH/0376

Study information

Scientific Title
A double-blind, randomised controlled trial of High Volume Saline Injections for chronic midportion Achilles Tendinopathy

Acronym
HVSIAT

Study objectives
High volume saline injections are an effective pain relieving treatment for people with longstanding pain in the achilles tendon which has not improved with a physiotherapy programme

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service, West Yorkshire, Leeds East, 26/10/2011, ref:11/YH/0376

Primary study design
Interventional

Study design
Double-blind randomised controlled trial and cohort study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Midportion Achilles Tendinopathy

Interventions
Experimental Arm: High volume saline injection

Patients randomised to this trial arm will receive an ultrasound guided steroid and local anaesthetic injection around the achilles tendon in the same way as the control arm patients. In addition they will receive an injected bolus of normal saline (through the same needle) of between 14-25ml until the new vessels seen on ultrasound scan disappear. They will be then given a programme of stretching and strengthening exercises in the same way as patients on the control arm.

Active Comparator: Control Arm

Patients on this trial arm will receive an ultrasound guided injection of steroid and local anaesthetic between Kager's fat pad and the achilles tendon. They will then be given a programme of stretching and strengthening exercises.

Patients on this trial arm will be offered the high volume saline injection at their 6 week follow up appointment after outcome measures have been taken by the blinded assessor.

The whole cohort of patients (control and treatment arms) will then be followed up at 12 and 40 weeks

Procedure descriptions:

Ultrasound guided injection of steroid and local anaesthetic
2ms of 0.5% Bupivocaine and 25mg of hydrocortisone given as a single bolus via a 21G needle using sterile technique. The injection will be placed into the space between Kagers fat pad and the anterior aspect of the achilles tendon, into the area of maximal neovascularisation as seen on ultrasound scan.

Procedure: High volume saline injection
After steroid and local anaesthetic has been delivered, a bolus of normal saline will also be infused into the space between Kager's fat pad and the achilles tendon through the same needle, using ultrasound guidance and sterile technique. At least 14mls will be given but up to 40mls could be used. Saline will be injected until the injector determines that the appearance of neovascularisation on ultrasound has disappeared.

Exercise programme
A bandage will be placed on the ankle for 48 hours and instructions given to rest the ankle. The patient will be verbally shown a programme of exercises to be done over the next 6 weeks to stretch the tendon and steadily build up load bearing on it. The exercises are also clearly shown on a leaflet which the patient takes home.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Pain, measured using 100mm Visual Analogue Pain Score at 6 weeks post injection

Key secondary outcome(s)
1. Foot and ankle function, measured using the Foot and Ankle Outcome Score (FAOS) at 6 weeks post injection
2. Health status, measured using EQ5D-3L at 6 weeks post injection
3. Diameter of symptomatic achilles tendon, measured by ultrasound scan at 6 weeks post injection
4. Neovascularisation grading: a grading of the amount of new vessel growth into the tendon as seen on ultrasound scan at 6 weeks post injection
5. The cohort of patients will have all outcome measures reviewed at 12 and 40 weeks to ensure resolution of symptoms and to look for evidence of symptom recurrence following injection

Completion date
12/03/2014

Eligibility

Key inclusion criteria
1. Age: 18+
2. More than 13 weeks of pain in the Achilles tendon area
3. Ongoing symptoms despite completing an eccentric loading exercise programme with a physiotherapist

4. Achilles tendon is tender to palpation
5. Tendon diameter greater than 0.7cm on ultrasound scan (indicating tendinopathy)
6. Evidence of neovascularisation on doppler ultrasound scan
7. Sufficient English literacy skills to complete consent and questionnaires

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Ultrasound evidence of tendon tear, intrasubstance defect or a previous history of tendon tear
2. Another co existing significant foot or ankle pathology, i.e. symptomatic osteoarthritis
3. Taking anticoagulant medication, clopidogrel or dipyridamole
4. A medical condition that would make treatment unsafe i.e. peripheral neuropathy, peripheral vascular disease or active infection
5. Previous achilles tendon surgery
6. Unable to give informed consent

Date of first enrolment
12/03/2012

Date of final enrolment
12/03/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Chapel Allerton Hospital
Leeds
United Kingdom
LS7 4SA

Sponsor information

Organisation
Leeds Community Healthcare Trust (UK)

ROR
https://ror.org/01776ep11

Funder(s)

Funder type
Government

Funder Name
National Institute of Health Research Flexibility and Sustainability Funding (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration