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Treating Achilles tendon pain

Submission date
17/11/2017

Recruitment status
No longer recruiting

Registration date
29/11/2017

Overall study status
Completed

Last Edited
27/11/2017

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Non-insertional Achilles tendinopathy is a common overuse injury which affects the mid-portion of the Achilles tendon. It is frequently seen in patients between the age of 30-50 years who participate in sport or other physically demanding leisure or work activities. It is characterised by pain impaired function and swelling around the affected tendon. The most common conservative treatment is an eccentric loading exercise programme which has been shown to give good short and long term results. However, the eccentric loading programme developed by Alfredson et al (1998) and the one currently preferred in practice is long (12 weeks) laborious (twice a day 7 days per week) and painful to perform. It has been shown to be more effective to the programme developed by Standish et al., (1996) which is carried out over the same duration but consists of both eccentric and static stretching exercises. Failure to respond to eccentric loading results in continued pain and discomfort which can be debilitating and, affect an individual's ability to return to sport or work in occupations which are physical demanding. In these patients treatment is usually escalated to some form of surgical intervention. With surgical complications and with the necessity for a long rehabilitation period, the consideration of an alternative non surgical option to eccentric loading is desirable. As an alternative some authors have shown a reduction in pain and improved function by injecting a high volume of saline around the effected tendon under ultrasound guidance. These studies have all been case series with no randomized controlled trials published to date. The aim of this study is to investigate the feasibility of carrying out a randomized controlled trial to evaluate the effectiveness of high volume ultrasound guided injections for the treatment of Non-insertional Achilles tendinopathy as an alternative to eccentric loading exercises.

Who can participate?
Adults aged 18 and older who have a Achilles tendinopathy.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the high volume ultrasound guided injection. Those in the second group carry out an eccentric loading exercise programme. Participants are followed up to evaluate the effectiveness of the intervention on pain and function, tendon thickness and neovascularity. Participants fill out questionnaires at the beginning of the study and at 3 months to evaluate pain and function. Neovascularity and tendon thickness will be measured using ultrasound.

What are the possible benefits and risks of participating?
Participants may benefit from improvements in their symptoms. No known risks have been reported in studies which have injected saline around a painful Achilles tendon. Some people might find the injection unpleasant but the addition of local anaesthetic should reduce any post injection pain. On rare occasions (less than 1%) people have been known to experience an allergic reaction (with the possibility of anaphylaxis) to the local anaesthetic. If participants have a known allergy to local anaesthetic they will be excluded from the study. If they experience a reaction during the study we are equipped to deal with your situation. In addition if something is identified on the scan such as a tear in the tendon, then further investigation and treatment will be initiated as required.

Where is the study run from?
Royal Infirmary of Edinburgh (UK)

When is the study starting and how long is it expected to run for?
September 2016 to September 2018

Who is funding the study?
University of Stirling (UK)

Who is the main contact?
Mr John Veto
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

version 3 November 2017

Study information

Scientific Title
A study to evaluate the feasibility of carrying out a randomised controlled trial to compare the effectiveness of high volume ultrasound guided injections verses eccentric loading exercises in reducing pain and improving function in patients with non-insertional Achilles tendinopathy

Study objectives
No hypothesis testing will form part of this feasibility study as recruitment rates are part of the primary outcome measures and will determine the necessary sample size required to carry out a larger scale study suitable powered to 0.8 with a level of significance of less than or equal to 0.05

Ethics approval required
Old ethics approval format

Ethics approval(s)
Submitted to South East Scotland REC O2-
IRAS project ID 206837
Approval pending

Study design
Feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
The study randomly assigns participants into two groups. One group receives the High Volume Ultrasound Guided Injection (HVUGI) whilst the other receives the current standard intervention of an eccentric loading programme. Randomisation takes place using an online programme developed and provided by sealed envelope®. This programme allocates participants with a unique identification code and randomly allocates them into two groups using a block design. The block sizes will be 4, 6, and 8. By using different block sizes removes the ability of the researchers to be able to work out sequencing whilst ensuring equivalent group size. The system

is accessed via a secure connection over the internet. This connection encrypts data between the Principle Investigators internet browser and the server. Online randomisation is achieved by the Principle Investigator entering the participant's unique identification code, providing email address and randomisation system password. On receipt of this information the system randomises the participant to treatment A or B. and notifies the principle investigator by email.

Group A – Eccentric Loading programme
Participants are required to complete the VISA- A questionnaire (appendix 6). In addition, an ultrasound scan is carried out to measure the tendon thickness (millimetres) and neovascularity (Ohberg score). This is carried out by the same consultant radiologist with expertise in diagnostic ultrasound.
Participants will be given an eccentric loading programme which details the type and number of repetitions required to be performed. They also are provided with a diary to record the compliance with the programme on a daily basis. The programme consists of a heel drop exercise carried out with the knee fully extended to eccentrically load the gastrocnemius and with the knee flexed to eccentrically load the soleus. The programme requires three sets of 15 repetitions of each exercise twice daily morning and evening for 12 weeks, and participants are advised that they should expect to experience some pain whilst performing the exercises.

At 12 weeks the participants complete the VISA-A questionnaire and an ultrasound scan is carried out again to measure tendon thickness and neovascularity. This isrecorded on the subject's data sheet. In addition all participants are sent a questionnaire following the 12 week appointment. This asks them to provide information of their experiences of the study interventions, and processes.

Group B- High Volume Ultrasound Guided Injection
Participants are asked to complete the VISA-A questionnaire. In addition prior to the administration of the HVUGI an ultrasound scan is carried out to measure the tendon thickness and neovascularity. All ultrasound scanningis carried out by the same consultant radiologist with expertise in diagnostic ultrasound.

The participants is positioned in a supine position with the knee flexed and the ankle in a neutral position. Under ultrasound guidance and using aseptic techniques a 21 gauge needle attached to a 30cm connecting tube is positioned between the anterior aspect of the Achilles tendon and Kager's fat pad. Under continued ultrasound guidance 40ml of injectable saline and 10ml of 0.5% Bupivacaine will be administered targeting the area of neovascularity. On removal of the needle a sterile dressing is applied.

A review appointment is given for 12 weeks. The VISA –A questionnaire is completed by the participants and an ultrasound scan to measure tendon thickness and neovascularity isperformed.

Following completion of the clinical study, all participants are asked to complete a short questionnaire. The purpose of the questionnaire is to gain an understanding of the participant's perceptions of the study and how they feel about the intervention that they were allocated too and any issues they had with the intervention and the outcome measures used. The questionnaire takes the form of a series of questions which vary between the two groups to reflect the two different intervention arms. It is posted to participants following their 12 week review, together with a prepaid envelop for them to return the questionnaire once completed. If participants have not returned the questionnaire after 2 weeks another one will be sent. The aim is for a response rate of at least 50% from each arm of the study.

Intervention Type
Device

Primary outcome measure
As this is a feasibility study the primary aims are to assess the proposed processes associated with carrying out a large scale RCT, and will review and evaluate three key elements, recruitment, follow up and safety:
1.1. Eligibility rate is assessed as the number of eligible subjects as a proportion of the total screened patients in a three month period.
1.2. Recruitment rate is assessed as the number of recruited patients as a proportion of the number of eligible patients within the three month period.
1.3. Test the proposed method of randomisation- even balance of subject numbers in each arm of the study.
1.4. To evaluate compliance with the intervention- the eccentric loading group are required to carry our relatively painful exercises for 12 weeks. Compliance is evaluated with the use of an adherence diary which will record frequency (number of sessions per week) and intensity (number of repetitions per session).
1.5. To explore patient's experiences of the HVUGI regarding pain associated with the procedure and the immediate post- operative period
1.6. To evaluate follow up rates as measured as the total number of recruited subjects who are followed to the end of the study period
1.7. Evaluate the outcome measures utilised in the study- VISA-A questionnaire/Ohbergs modified neovascularity score
1.8. Record any adverse reactions to the HVUGI or the eccentric loading programme

Secondary outcome measures
1. The effect of high volume ultrasound guided injections compared with eccentric loading on pain and function in subjects with non-insertional Achilles tendinopathy is meaured using the VISA-A questionnaire
2. The effect of high volume ultrasound guided injection compared with eccentric loading on tendon thickness in subjects with non-insertional Achilles tendinopathy is measured using the Modified Ohberg neovascularisation Score
3. The effect of high volume ultrasound guided injections compared with eccentric loading on neovascularity in subjects with non-insertional Achilles tendinopathy is measurd using the ultrasound scanners digital measuring device

Overall study start date
08/09/2016

Completion date
08/09/2018

Eligibility

Key inclusion criteria
1. Male or female
2. Aged 18 or over
3. Capacity to give informed consent
4. Clinical diagnosis of unilateral non- insertional Achilles tendinopathy / plus diagnostic ultrasound confirmation. Clinical diagnosis would include the following:
4.1. Pain and tenderness on palpation of the Achilles tendon 2-6cm from the insertion in to the

calcaneus.
4.2. Evidence of tendon thickening on palpation of the Achilles tendon.
4.3. Negative Simmonds-Thompson test.
4.4. Painful arc test
5. English is first language

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Concurrent musculoskeletal ankle problems.
2. Have a diagnosed rheumatological disorder.
3. Suffered partial /complete tear of the Achilles tendon
4. Previous injection for non- insertional Achilles tendinopathy
5. Previous surgery to the Achilles tendon.
6. Patients with bilateral non insertional Achilles tendinopathy.
7. Currently taking quinolone antibiotics
8. Previous allergy to local anaesthesia.
9. English is not the first language

Date of first enrolment
15/01/2018

Date of final enrolment
11/05/2018

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Royal Infirmary of Edinburgh
51 Little France Crescent
Old Dalkeith Road

Edinburgh
United Kingdom
EH16 4SA

Sponsor information

Organisation
University of Stirling

Sponsor details
Research and Innovation Services
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Sponsor type
University/education

ROR
https://ror.org/045wgfr59

Funder(s)

Funder type
University/education

Funder Name
University of Stirling

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer reviewed journal around 1 year after trial end date.

Intention to publish date
08/09/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date