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Steroid injection in plantar fasciitis

Submission date	Recruitment status	[_] Prospectively registered
11/10/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/11/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/07/2013	Musculoskeletal Diseases	

Plain English summary of protocol

Background and study aims
Plantar fasciitis is a very common cause of heel pain. Typically the pain is worse in the mornings and after inactivity. The plantar fascia is a thick, strong band of elastic tissue on the sole of the foot which acts as a shock absorber and provides support for the arches of the foot.
Initial treatments include gel insoles or supports for the shoe or stretching exercises but for those patients in whom the pain persists, steroid injection is sometimes used as the next treatment step.
Despite this some people do not respond to these injections. We are not sure if this is because the injection is not in exactly the right place or because the steroid itself is not effective. This study has been designed to answer two questions 1) Does steroid injection really work 2) Are the results better if we use an ultrasound scanner (similar to that used for expectant mothers) to help with the injection?

Who can participate?
Patients aged over 18 years with a clinical diagnosis of plantar fasciitis will be invited to participate.

What does the study involve?
Patients will be asked to attend the rheumatology outpatient department in Musgrave Park Hospital, Belfast on three separate occasions.
On the first occasion, patients will be asked to complete a questionnaire, which will ask questions about heel pain, occupation and exercise. Patients will then be examined by a specialist rheumatology podiatrist who will take some foot measurements. Next a doctor will examine the foot using an ultrasound machine. This will be a painless procedure, where gel will be applied to the skin, and a smooth probe will be passed over the heel. Finally, patients will receive one of three treatment options:
1. Injection of heel with steroid (20mg methylprednisolone) (depomedrone) without ultrasound guidance (this has been the traditional approach)
2. Injection of heel with steroid (20mg methylprednisolone) (depomedrone) using ultrasound to guide the injection.
3. Injection of heel with sterile salt water (no steroid) using ultrasound guidance.
All three techniques will first use local anaesthetic to numb the heel so that it will be as painless as possible.
Patients will not know which treatment they are receiving so that we will be better able to work

out the response (this is called a blinded study and it gives more accurate results). The doctor or podiatrist doing the assessments will not know what treatment the patient has received either. On the second and third occasions, 6 weeks and 12 weeks after the injection, patients will be asked to complete another questionnaire, to assess how the injection has affected the pain. another ultrasound scan to assess the heel will be done.
The drug being tested is called methylprednisolone acetate, another name by which it may be known is Depomedrone. This drug has been used for the treatment of arthritis and heel pain for many years. The drug will be in a liquid form and is injected into the heel. Patients will be able to continue with all of their usual medication and painkillers.

What are the possible benefits and risks of participating?
The steroid injection may reduce the pain in the heel for a period of time or indeed longer. The information that we get from this study may help us to target the use of steroid injections in patients with heel pain and we hope to find out whether ultrasound is useful or not.
Steroid injections used in this study have been used in the treatment of arthritis and heel pain for many years. While joint injections of steroids are regarded as safe to use in patients with arthritis side effects can occur. Repeated or too many injections can cause shrinkage of the fat pad in the heel above the plantar fascia but this is very unusual. Also there is a theoretical risk of rupturing the plantar fascia with a steroid injection but again this happens only very very rarely. There is no risk with injecting sterile water. The use of ultrasound as an investigation has been in medicine for many years and there are no perceived side effects to this investigation.

Where is the study run from?
The study will take place within the Belfast Health and Social Care Trust and patients will be recruited from the Podiatry department and via GP referrals to the rheumatology service.

When is the study starting and how long is it expected to run for?
The study will run from 2008 until 2011.

Who is funding the study?
No external funding is being received. The Belfast Trust is paying for any incidental costs.

Who is the main contact?
Dr Elisabeth Ball
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Contact information

Type(s)
Scientific

Contact name
Dr Allister Taggart

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
A randomised placebo controlled trial to compare ultrasound guided with palpation guided steroid injection in plantar fasciitis

Study objectives
The plantar fascia is a fibrous band on the undersurface of the foot which acts as a shock absorber and a support for the arches of the foot. It may become inflammed leading to fasciitis which manifests as severe localised heel pain which is typically worse in the mornings and after inactivity and worsens again with overuse. The pain is debilitating and has a significant impact on quality of life and work capacity.

To compare steroid injection with placebo in the management of plantar fasciitis, to compare ultrasound guided steroid injection with palpation guided steroid injection and to investigate the overall role of ultrasound in the management of plantar fasciitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval was obtained from the Northern Ireland Regional Ethics Committee ORECNI) in Aug 2008, Ref: 08/NIR01/47

Study design
Randomised double blind placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact Dr Elisabeth Ball (Elisabethball21@gmail.com) to request a patient information sheet

Health condition(s) or problem(s) studied
Plantar fasciitis

Interventions
1. Ultrasound guided steroid group - patients will be given a steroid injection with the use of direct ultrasound guidance for needle insertion via the posterior heel approach
2. Palpation guided steroid injection - patients will be given a steroid injection via the posterior heel approach with the needle directed towards the area of maximum pain. A 'sham' ultrasound technique will be used in that the probe will be placed on the foot so that the patients will not be aware of which type of injection they are receiving.
3. Ultrasound guided placebo group - patients will receive an injection of sterile water under ultrasound guidance - syringes will be taped by an independent observer so that the investigator doing the injections is blinded as to whether he is injecting steroid or placebo

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Patient reported pain levels (Visual Analogue scale) at 6 weeks and 12 weeks

Secondary outcome measures
1. Heel Tenderness Index (assessed by the physician)
2. Ultrasound appearances of the plantar fascia at 6 weeks and 12 weeks

Overall study start date
05/11/2008

Completion date
17/06/2011

Eligibility

Key inclusion criteria
Patients aged over 18 with a clinical diagnosis of plantar fasciitis

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
90

Key exclusion criteria
1. Any patients with a history of inflammatory arthritis or psoriasis
2. Who have ever previously received a steroid injection

Date of first enrolment
05/11/2008

Date of final enrolment
17/06/2011

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Dept of Rheumatology
Belfast
United Kingdom
BT9 7JB

Sponsor information

Organisation
Belfast Health and Social Care Trust (UK)

Sponsor details
Research Support
King Edward Building, 2 nd Floor
Royal Victoria Hospital
Belfast
Northern Ireland
United Kingdom
BT12 6BA

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02tdmfk69

Funder(s)

Funder type
Charity

Funder Name
Belfast Health and Social Care Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2013		Yes	No