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Is the use of bupivacaine hydrochloride 0.5% an effective treatment for the relief of chronic plantar fascial pain?

Submission date
29/09/2006

Recruitment status
No longer recruiting

Registration date
29/09/2006

Overall study status
Completed

Last Edited
06/03/2015

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Contact details
Trauma
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0265105806

Study information

Scientific Title
Is the use of bupivacaine hydrochloride 0.5% an effective treatment for the relief of chronic plantar fascial pain?

Study objectives
Injection(s) of bupivacaine hydrochloride 0.5% is an effective treatment for patients with chronic plantar fascial pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Musculoskeletal Diseases: Plantar fasciitis

Interventions
It is proposed that 80 subjects presenting with heel Pain that have been referred for Podiatric assessment and intervention will be recruited to the study.

Those patients who are diagnosed with plantar fasciitis according to a recognised criteria, and who consent to the study, will have their pain intensity assessed using a Visual Analogue Scale (VAS).

The patients will then be randomized into experimental and control groups. The recruits will then receive the proposed treatment regime and will have their VAS assessed at each visit.

The researcher will remain blind to the recruits VAS score and both the researcher and subject will be blind to the injected agent. The use of local anesthetic injections as a therapeutic intervention is normal practice within the Podiatry department.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Bupivacaine hydrochloride

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
26/02/2002

Completion date
26/02/2008

Eligibility

Key inclusion criteria
The cohort of patients will be recruited from appropriate referrals received from General Practitioners within Primary Care, and Consultants within the UHB Trust for Podiatric assessment and intervention.
Volunteers will be provided with information sheets and informed consent required in writing will be obtained prior to the study. Volunteers will be made aware that their withdrawal form the study at any stage will not adversely affect their future treatment.
Inclusion criteria: Patients over 18 years of age with pain over the medial aspect of the heel, and who fulfill the criteria set down by Saxelby et al (1997).
The Podiatry Department has access to interpreters if there are issues relating to language problems.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Patients with a known sensitivity to local anesthetics
2. Patents with liver disease
3. Patients with kidney disease
4. Patients with broken skin/skin lesions/infection around the injection site
5. Pregnant women
6. Patients on anticoagulation therapy

Date of first enrolment
26/02/2002

Date of final enrolment
26/02/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Selly Oak Hospital
Birmingham
United Kingdom
B29 6JD

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Birmingham NHS Trust

Funder Name
NHS R&D Support Funding

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