ISRCTN86484960 https://doi.org/10.1186/ISRCTN86484960

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
Mr KM Porter

Contact details
Trauma
Selly Oak Hospital
Birmingham
United Kingdom
B29 6JD

Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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

United Kingdom

England

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

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Birmingham NHS Trust

Funder Name
NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration