

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
Selly Oak Hospital
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B29 6JD

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 from 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. Patients 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