

Evaluation of the efficacy of buprenorphine injection around the stellate ganglion in pain syndromes of the upper body-half

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/04/2008	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Andreas Goebel

Contact details
c/o Pain Relief Unit
The Churchill
Headington
Oxford
United Kingdom
OX3 7LJ
+44 (0)1865 226161
andreasgoebel@rocketmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Study objectives

1. To determine if 0.025 mg buprenorphine, a highly lipophilic morphine derivate, is more efficient than saline in relieving chronic, non-nociceptive pain when injected in proximity to the stellate ganglion. The stellate ganglia are collections of autonomic nerve cells and synapses located on either side of the neck.
2. A minimally traumatising method for injection of the stellate ganglion, not previously been published in the English literature will be used; this method is applied in German pain clinics. Our objective is to ascertain the usefulness of this method in conjunction with stellate opioid injections.

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)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Pain

Interventions

Two interventions:

1. Normal injection into buttocks
2. Injection into neck

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Buprenorphine

Primary outcome measure

1. Pain reduction over the first 8 hours following stellate injection, as calculated from the median of four, two-hourly measurements of present pain reduction using a visual analogue scale (VAS) and compared between buprenorphine and placebo stellate injections
2. Absolute pain levels as expressed using a VAS scale and calculated from the median of four, two-hourly measurements of present pain intensity (PPI), each divided by the pre-injection PPI and compared between buprenorphine and placebo stellate injections

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/10/2002

Completion date

15/11/2004

Eligibility**Key inclusion criteria**

Not provided at time of registration

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

60

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/10/2002

Date of final enrolment

15/11/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

c/o Pain Relief Unit

Oxford

United Kingdom

OX3 7LJ

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

Oxford Radcliffe Hospitals NHS 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	01/04/2008		Yes	No