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

Submission date	Recruitment status	[_] Prospectively registered
12/09/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/04/2008	Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0176115639

Study information

Scientific Title

Study objectives
1. To determine if 0.025 mg buprenorphine, a highly lipohilic 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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
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

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

Completion date
15/11/2004

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

Study participating centre
c/o Pain Relief Unit
Oxford
United Kingdom
OX3 7LJ

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Oxford Radcliffe Hospitals NHS Trust (UK)

Results and Publications

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