

A randomised placebo-controlled trial of the analgesic efficacy of epidurally administered clonidine following spinal surgery.

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/08/2009	Condition category Surgery	<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 Andrew D Farmery

Contact details
Nuffield Department of Anaesthetics
Radcliffe Infirmary
Woodstock Road
Oxford
United Kingdom
OX2 6HD
+44 (0)1865 311188
andrew.farmery@nda.ox.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0176120400

Study information

Scientific Title

Study objectives

1. To test the hypothesis that the efficacy of epidurally administered clonidine does not differ from that of epidurally administered placebo.
2. To determine whether the use of epidurally administered clonidine would produce sufficient benefit to our patients to justify altering our practice to include it.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by Oxford Research Ethics Committee.

Study design

Randomised placebo controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Surgery: Analgesia

Interventions

Epidurally administered clonidine vs epidurally administered placebo.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

clonidine

Primary outcome measure

Pain score, morphine consumption (PCA), nausea, vomiting, blood pressure.

Secondary outcome measures

Not provided at time of registration

Overall study start date

07/10/2002

Completion date

30/01/2005

Eligibility

Key inclusion criteria

Added June 2008:

Patients scheduled for elective lumbar decompression or discectomy surgery.

Participant type(s)

Patient

Age group

Adult

Sex

Not Specified

Target number of participants

30 patients, 30 controls, total 60.

Key exclusion criteria

Added June 2008:

1. Patients taking strong opioids preoperatively or with chronic pain states
2. Patients under 18 years of age

Date of first enrolment

07/10/2002

Date of final enrolment

30/01/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Nuffield Department of Anaesthetics
Oxford
United Kingdom
OX2 6HD

Sponsor information

Organisation
Department of Health

Sponsor details
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
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	01/02/2009		Yes	No