ISRCTN52323712 https://doi.org/10.1186/ISRCTN52323712

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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 25/08/2009	**Condition category** Surgery	

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
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

Study type(s)
Treatment

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

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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health

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	01/02/2009		Yes	No