

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

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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