# Epidural steroid injection in chronic lumbar back pain: a cross-over, single-blinded study of methyl-prednisolone 80mg versus methyl-prednisolone 40mg

Submission date	Recruitment status	Prospectively registered		
28/09/2007	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
28/09/2007	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
01/10/2012	Musculoskeletal Diseases			

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr A Ravenscroft

#### Contact details

Anesthetics Department City Hospital Hucknall Road Nottingham United Kingdom NG5 1PB

# Additional identifiers

Protocol serial number N0192187922

# Study information

Scientific Title

#### Study objectives

Does 40mg of epidural methyl-prednisolone produce an equivalent improvement in disability scores when compared to 80mg of epidural methyl-prednisolone?

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

#### Study design

Randomised single-blinded cross-over trial

#### Primary study design

Interventional

### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Musculoskeletal Diseases: Low back pain

#### **Interventions**

- 1. 80mg methyl-prednisolone repeated three months later with 40mg dose
- 2. 40mg methyl-prednisolone repeated three months later with 80mg dose

## Intervention Type

Drug

#### Phase

**Not Specified** 

## Drug/device/biological/vaccine name(s)

methyl-prednisolone

#### Primary outcome(s)

Evidence that a reduced dose of methyl-prednisolone given epidurally does not cause a significant worsening of the primary outcome measure ie the Oswestry Low Back Pain Disability Index.

# Key secondary outcome(s))

Not provided at time of registration

# Completion date

28/02/2007

# **Eligibility**

#### Key inclusion criteria

Patients attending Nottingham City Hospital Day Case Unit, with chronic back pain who are presenting for repeat epidural steroid injection as part of their chronic pain management programme.

#### Participant type(s)

**Patient** 

## Healthy volunteers allowed

No

#### Age group

**Not Specified** 

#### Sex

**Not Specified** 

#### Key exclusion criteria

- 1. Blood clotting disorder
- 2. Anticoagulant (Warfarin) use

#### Date of first enrolment

24/05/2006

#### Date of final enrolment

28/02/2007

# Locations

#### Countries of recruitment

United Kingdom

England

## Study participating centre Anesthetics Department

Nottingham United Kingdom NG5 1PB

# Sponsor information

#### Organisation

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

# Funder(s)

# Funder type

Government

#### Funder Name

Nottingham University Hospitals NHS Trust (UK), NHS R&D Support Funding

# **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	27/09/2012	Yes	No
Other publications	pilot study	01/07/2011	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes