

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

<b>Submission date</b> 28/09/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 28/09/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 01/10/2012	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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**  
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?
<a href="#">Results article</a>	results	27/09/2012		Yes	No
<a href="#">Other publications</a>	pilot study	01/07/2011		Yes	No