ISRCTN43299460 https://doi.org/10.1186/ISRCTN43299460

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

Submission date
28/09/2007

Recruitment status
No longer recruiting

Registration date
28/09/2007

Overall study status
Completed

Last Edited
01/10/2012

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Primary study design
Interventional

Study design
Randomised single-blinded cross-over trial

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