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

Contact name
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Anesthetics Department
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
Not provided at time of registration

Overall study start date
24/05/2006

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
60

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
England

United Kingdom

Study participating centre
Anesthetics Department
Nottingham
United Kingdom
NG5 1PB

Sponsor information

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

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
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dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Other publications	pilot study	01/07/2011		Yes	No
Results article	results	27/09/2012		Yes	No