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Evaluation of effect of sedation on diagnostic lumbar facet joint nerve blocks

Submission date
27/09/2005

Registration date
17/11/2005

Last Edited
13/10/2008

Recruitment status
No longer recruiting

Overall study status
Completed

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol #6

Study information

Scientific Title

Study objectives
To demonstrate that sedation has no effect on the validity of diagnostic lumbar facet joint nerve blocks.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic low back pain

Interventions
Intravenous injection of sodium chloride solution, midazolam, or fentanyl prior to lumbar facet joint nerve blocks under fluoroscopy.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Sodium chloride solution, midazolam, or fentanyl

Primary outcome measure
For a small proportion of patients with chronic low back pain, the administration of sedation with midazolam or fentanyl can be a confounding factor in the diagnosis of lumbar facet joint pain. The study shows that an intravenous preoperative sedative dose of a narcotic such as

fentanyl or an anxiolytic such as midazolam is no more likely to cause a small proportion of patients to report false positive pain relief with active motion testing than sodium chloride placebo.

Secondary outcome measures
The study suggests that prudent administration of midazolam or fentanyl to patients who are not relaxed may not have any significant adverse effect on the diagnostic validity of controlled comparative local anesthetic blocks.

Overall study start date
02/02/2004

Completion date
30/06/2004

Eligibility

Key inclusion criteria
1. Subjects were between 18 and 90 years of age
2. Subjects with a history of chronic, function limiting, low back pain of at least 6 months duration
3. Subjects able to give voluntary, written informed consent to participate in the investigation
4. Subjects who, in the opinion of the investigator, are able to understand the investigation and /or cooperate with the investigational procedures
5. Patients who have undergone diagnostic facet joint blocks and the diagnosis of lumbar facet joint pain has been previously confirmed

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
180 subjects, randomized into 3 groups with equal distribution

Key exclusion criteria
1. Patients without lumbar facet joint pain
2. Patients with uncontrolled major depression or uncontrolled psychiatric disorders
3. Pregnant or lactating women
4. Patients with multiple complaints involving multiple other problems which have overlapping pain complaints
5. Patients unable to achieve proper positioning or unable to understand informed consent and protocol
6. Patients with a history of adverse reaction to either midazolam or fentanyl

Date of first enrolment
02/02/2004

Date of final enrolment
30/06/2004

Locations

Countries of recruitment
United States of America

Study participating centre
2831 Lone Oak Road
Paducah, KY
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42003

Sponsor information

Organisation
Ambulatory Surgery Center and Pain Management Center of Paducah (USA)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.thepainmd.com

Funder(s)

Funder type
Hospital/treatment centre

Funder Name

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?
Results article	results	01/07/2004		Yes	No