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A randomized, prospective, double-blind, placebo-controlled evaluation of the effect of sedation on combined diagnostic cervical and lumbar facet joint nerve blocks

Submission date
21/06/2005

Recruitment status
No longer recruiting

Registration date
22/06/2005

Overall study status
Completed

Last Edited
16/08/2011

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

Study information

Scientific Title

Study objectives
To demonstrate the lack of effect of sedation on the validity of diagnostic cervical and 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)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Back pain

Interventions
Patients with combined chronic neck and low back pain of facet joint origin identified with controlled, comparative local anesthetic nerve blocks will receive 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 and fentanyl

Primary outcome measure
1. Comparison of midazolam and fentanyl with placebo (sodium chloride injection)
2. To demonstrate a lack of clinically significant difference in the treatment groups after 10 minutes post-treatment in the:
2.1 Numeric pain scale in neck and low back
2.2 Ability to perform the painful movements in neck and low back, which were painful prior to intravenous administration of sedation

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/05/2004

Completion date
31/10/2005

Eligibility

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

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
A total of 60 patients, randomized into 3 groups with equal size

Key exclusion criteria
1. Absence of combined cervical and lumbar facet joint pain
2. Uncontrolled major depression or uncontrolled psychiatric disorders

3. Women who are pregnant or lactating
4. Patients with multiple complaints involving multiple other problems which have overlapping pain complaints
5. Inability to achieve appropriate positioning and inability to understand informed consent and protocol
6. History of adverse reaction to either midazolam or fentanyl

Date of first enrolment
01/05/2004

Date of final enrolment
31/10/2005

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
Institutional Review Board of Ambulatory Surgery Center (USA)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02swzn148

Funder(s)

Funder type
Not defined

Funder Name
No other external support or funding were received in completion of this study.

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	01/01/2006		Yes	No