ISRCTN52746887 https://doi.org/10.1186/ISRCTN52746887

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

Submission date
27/09/2005

Registration date
17/11/2005

Last Edited
02/10/2008

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 #5

Study information

Scientific Title

Study objectives
To demonstrate sedation has no effect on the validity of diagnostic cervical 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 neck pain

Interventions
Intravenous injection of sodium chloride solution, midazolam, or fentanyl prior to cervical 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
The administration of sedation with midazolam or fentanyl could be a confounding factor in the diagnosis of cervical facet joint pain in patients with chronic neck pain. However, if ≥80% pain relief with the ability to perform prior painful movements is used as the diagnostic standard, the

effect of sedation on validity may be extremely low. In contrast, a significant number of patients may present as false-positives if ≥50% pain relief with ability to perform prior painful movements is used as the diagnostic criteria.

Secondary outcome measures
Prudent administration of midazolam only to patients who are not relaxed may not have significant adverse effect on the diagnostic validity of controlled comparative local anesthetic blocks. On the other hand, fentanyl could confound the diagnosis with false-positive results in a significant proportion of patients.

Overall study start date
02/02/2004

Completion date
30/04/2004

Eligibility

Key inclusion criteria
1. Subjects were between 18 and 90 years of age
2. Subjects had a history of chronic, function limiting, neck pain of at least 6 months duration
3. Subjects were 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. Subjects who had undergone diagnostic facet joint blocks and the diagnosis of cervical 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
180 patients, randomized into 3 groups with equal distribution.

Key exclusion criteria
1. Subjects without cervical facet joint pain
2. Subjects with uncontrollable major depression or uncontrolled psychiatric disorders
3. Pregnant or lactating women
4. Subjects with multiple complaints involving multiple other problems with overlapping pain complaints
5. Subjects unable to achieve appropriate positioning and inability to understand informed

consent and protocol
6. Subjects with a history of adverse reaction to either midazolam or fentanyl

Date of first enrolment
02/02/2004

Date of final enrolment
30/04/2004

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

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	01/10/2004		Yes	No