

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

Submission date 27/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 17/11/2005	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 02/10/2008	Condition category Musculoskeletal Diseases	☐ 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
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

Study type(s)

Treatment

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(s)

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 $\geq 80\%$ 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 $\geq 50\%$ pain relief with ability to perform prior painful movements is used as the diagnostic criteria.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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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Sponsor information

Organisation

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

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

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	01/10/2004		Yes	No