

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

Submission date 27/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 17/11/2005	Overall study status Completed	☐ Protocol
Last Edited 13/10/2008	Condition category Musculoskeletal Diseases	☐ Statistical analysis plan
		☒ 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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
United States of America
42003

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	01/07/2004		Yes	No