

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	☐ Prospectively registered
Registration date 22/06/2005	Overall study status Completed	☐ Protocol
Last Edited 16/08/2011	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

Contact name

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Additional identifiers

Protocol serial number

7

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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
United States of America
42003

Sponsor information

Organisation

Institutional Review Board of Ambulatory Surgery Center (USA)

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

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