

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

<b>Submission date</b> 27/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 17/11/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/10/2008	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Laxmaiah Manchikanti

**Contact details**  
2831 Lone Oak Road  
Paducah, KY  
United States of America  
42003  
+1 270 554 8373  
drm@asipp.org

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

### **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 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 measure**

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.

### **Secondary outcome measures**

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.

### **Overall study start date**

02/02/2004

### **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

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

180 subjects, randomized into 3 groups with equal distribution

### **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)

**Sponsor details**

2831 Lone Oak Road

Paducah, KY

United States of America

42003

+1 270 554 8373

drm@asipp.org

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.thepainmd.com>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

## 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?
<a href="#">Results article</a>	results	01/07/2004		Yes	No