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A randomised, prospective, double-blind controlled study evaluating the effectiveness of spinal endoscopy with adhesiolysis for the treatment of chronic low back pain

Submission date
10/06/2005

Recruitment status
No longer recruiting

Registration date
15/06/2005

Overall study status
Completed

Last Edited
25/09/2009

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

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

Study information

Scientific Title

Study objectives
1. To demonstrate clinically significant improvements in the spinal endoscopy with adhesiolysis patients compared to those patients randomized to the control group who did not receive spinal endoscopy therapy, but received epidural injections. Improvement will be assessed in relation to the clinical outcome measures of pain and function.
2. To evaluate and compare the adverse event profile in both groups

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)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic low back pain and lower extremity pain

Interventions
Spinal endoscopy with adhesiolysis using Myeloscope® (Visionary Biomedical Inc)
Epidural local anesthetic with steroid

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
To demonstrate a clinically significant difference between the treated patients and those patients randomized to the control group in the Physical Function and Pain at 1, 3, 6 and 12 months post treatment

Secondary outcome measures
To assess adverse events in both groups

Overall study start date
23/01/2002

Completion date
31/12/2003

Eligibility

Key inclusion criteria
1. Candidate is between 18 and 65 years of age
2. Subjects with a history of chronic, function limiting low back pain of at least six 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, co-operate with the investigational procedures and are willing to return to the clinic for all the required post-operative follow-ups
5. The subject has not had recent surgical procedures within the last three months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Maximum 100 patients total - Study included total of 83 patients

Key exclusion criteria
1. Large contained or sequestered herniation. A small contained herniation is permitted (<4 mm).
2. Cauda Equina symptoms and/or compressive radiculopathy
3. Narcotic use of no greater than Hydrocodone 100 mg/day, Methadone of 60 mg or Morphine 100 mg, or dose equivalent
4. Uncontrolled major depression or uncontrolled psychiatric disorders
5. Uncontrolled or acute medical illnesses including coagulopathy, renal insufficiency, chronic liver dysfunction, history of gastrointestinal bleeding or ulcers, urinary sphincter dysfunction,

progressive neurological deficit, infection, increased intracranial pressure, pseudotumor cerebri, intercranial tumors, unstable angina, and severe chronic obstructive pulmonary disease
6. Chronic severe conditions that could interfere with the interpretations of the outcome assessments for pain and bodily function
7. Women who are pregnant or lactating
8. Subjects who have participated in a clinical study with an investigational product within 30 days of enrollment
9. Patients with multiple complaints involving hip osteoarthritis, will not be amenable to study due to the overlap of pain complaints
10. Inability to achieve appropriate positioning and inability to understand informed consent and protocol
11. History of adverse reaction to local anesthetic or anti-inflammatory drugs or history of gastrointestinal bleeding or ulcers

Date of first enrolment
23/01/2002

Date of final enrolment
31/12/2003

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)

Sponsor details
2831 Lone Oak Road
Paducah, Kentucky
United States of America
42003
+1 270 554 8373
painmgmt@apex.net

Sponsor type

Hospital/treatment centre

ROR
https://ror.org/02swzn148

Funder(s)

Funder type
Industry

Funder Name
The Myeloscope® Spinal Endoscopy Introducer and Video-Guided Catheter System used in this study were provided by Clarus Medical Systems, Inc. No other external support or funding were received in completion of this study.

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	06/07/2005		Yes	No