

Prospective randomized controlled trial of selective nerve root blockade in patients with acute or subacute sciatica

Submission date 10/02/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 27/02/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/08/2021	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RS2001/02-026 (Workers Compensation Board of British Columbia Research Secretariat)

Study information

Scientific Title

Prospective randomized controlled trial of selective nerve root blockade in patients with acute or subacute sciatica

Acronym

Transforaminal epidural steroid injection in Acute Radicular Pain (TARP)

Study objectives

Fluoroscopically guided transforaminal epidural steroid injection (TFESI) into the immediate vicinity of the affected nerve root in patients with acute lumbar disc herniation and radicular pain is associated with:

1. Improvement in pain and functional status and
2. Reduction in rate of progression to surgery

Ethics approval required

Old ethics approval format

Ethics approval(s)

Univeristy of British Columbia Clinical Research Ethics Board Approval was obtained.
Number C02-0365

Study design

Prospective double-blind randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Acute lumbar intervertebral disc herniation

Interventions

Patients were randomized to either 1.0 cc Celestone (40 mg/mL) plus 1.0 cc 0.5% bupivacaine (treatment), or 1.0 cc sterile saline plus 1.0 cc 0.5% bupivacaine (control).

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. LegPain40: LegPain40 is a 0 to 40 aggregate pain score based on severity of pain/discomfort in the leg (sciatica) over the past week when it was i) most severe, ii) least severe, iii) average, and iv) at present time, with 0 being no pain and 10 being pain as bad as it can be.
2. BackPain10: BackPain10 is a 0 to 10 scale of severity of back pain/discomfort over the past week when it was most severe.
3. Modified Roland-Morris Disability Questionnaire (RDQ): RDQ measures the degree to which a patients functional capacity is limited by back pain. The modified RDQ is a 23-item questionnaire developed specifically for patients with sciatica, and has good internal consistency, validity, and responsiveness in this population of patients.

Secondary outcome measures

Rate of progression to surgery

Overall study start date

30/05/2003

Completion date

30/04/2005

Eligibility**Key inclusion criteria**

1. Age 19 years or older
2. Pain in a single lower extremity below the level of the knee of less than 18 week duration
3. Presence of at least one of the following on physical examination - positive straight leg test, motor deficit, or reflex abnormality
4. Presence of a herniated nucleus pulposus (HNP) demonstrated by CT or MRI at a level and side corresponding to symptoms and signs

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

88

Key exclusion criteria

1. History of an adverse reaction to local anaesthetic or steroids
2. Any spinal injection within the last 6 months
3. Cauda equina syndrome, progressive neurological deficit, or lower extremity weakness of less than 3/5

Date of first enrolment

30/05/2003

Date of final enrolment

30/04/2005

Locations

Countries of recruitment

Canada

Study participating centre

Laurel Rheumatology Group

Vancouver, BC

Canada

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Sponsor information

Organisation

WorkSafeBC Research Secretariat (Canada)

Sponsor details

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Sponsor type

Government

Website

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Funder(s)

Funder type

Government

Funder Name

Workers Compensation Board of British Columbia Research Secretariat (RS2001/02-026)(Canada)

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