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

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 10/02/2007 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 27/02/2007 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 20/08/2021 | Musculoskeletal Diseases | [ ] 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% bupivicaine (treatment), or 1.0 cc sterile saline plus 1.0 cc 0.5% bupivicaine (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**
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## Sponsor information

**Organisation**
WorkSafeBC Research Secretariat (Canada)

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Government

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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