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SLURP: Steroidinjections in LUmbosacral Radicular Syndrome

Submission date	Recruitment status	[ ] Prospectively registered
20/12/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/12/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/11/2008	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
1705; NTR342

Study information

Scientific Title
Segmental epidural steroid injections for lumbosacral radicular syndrome: a randomised controlled trial comparing cost-effectiveness of a segmental epidural injection with usual care for patients with lumbosacral radicular syndrome (LRS) in general practice

Acronym
SLURP

Study objectives
Adding segmental steroid injections to usual care in the treatment of acute lumbosacral radicular syndrome will reduce pain and fasten recovery in general practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Randomised, single-blind, active controlled, parallel group 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
Lumbosacral Radicular Syndrome

Interventions
1. Intervention group: care as usual, combined with one or two segmental epidural corticosteroid injections (80 mg kenacort)
2. Control group: care as usual

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Kenacort

Primary outcome measure
1. Pain in back and/or leg, while walking, standing, lying down and night pain using a numerical rating scale (NRS) (0 - 10)
2. Severity of main complaint NRS (0 - 10)
3. Perceived recovery (NRS 0 - 10, complete recovery-severe deterioration)

Secondary outcome measures
1. Mobility, which the Roland-Morris Disability Questionnaire
2. Quality of life, measured with thr 36-item short form health survey (SF-36)
3. Primary and secondary health care costs

Overall study start date
01/09/2005

Completion date
01/09/2008

Eligibility

Key inclusion criteria
1. Answering to the definition of lumbosacral radicular syndrome as described by the Guidelines of the Dutch College of General Practitioners (see introduction). The GP diagnoses the patient on grounds of history and physical examination.
2. Underwent usual medical care for lumbosacral radicular syndrome with insufficient response in one to two weeks of treatment. Inadequate response is, in accordance with the guideline of the Dutch college of general practitioners, left to the agreement of patients and GPs together.
3. Aged between 18 and 60 years old

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
80

Key exclusion criteria

1. Pain that has lasted for more than one month before the patient presents to the GP (we want to include acute patients)
2. Having experienced a previous episode of lumbosacral radicular syndrome in the twelve months before the study
3. Previously having undergone spinal surgery. Previous spinal surgery will have caused adhesions in the patients' vertebrae, making the approach and the application of the epidural injection much more difficult. Chances of complications are a lot higher and the risk of needle misplacing increases.
4. Complaints arising after trauma. Patients who developed lumbosacral radicular syndrome as a result of trauma may have pathology that needs additional diagnostic imaging and treatment other than injections.
5. Maintenance therapy of oral corticosteroids. Apart from possible interference with the study results, patients on maintenance therapy of oral corticosteroids have a higher risk that their symptoms may be caused by osteoporosis which may need additional diagnostic imaging.
6. Oral anticoagulant therapy or bleeding disorders. Treatment with acenocoumarol and/or other anticoagulants increases the risk of bleeding. Since this risk is not as high with platelet aggregation inhibitors, we will not exclude patients on acetylsalicyclic acid or non-steroidal anti-inflammatory drug (NSAID) maintenance therapy.
7. Paresis or cauda equina syndrome. Lower extremity paresis and especially cauda equina syndrome are indications for immediate referral to a neurosurgeon.
8. Morbid obesity: body mass index (BMI) (weight/square length) greater than 35 In these patients, back pain complaints are much more likely to have other causes than lumbosacral radicular syndrome. Besides, administration of SESI is much more difficult in obese patients since the epidural space is harder to find and the needle may be to short. This increases the risk of false-negative results, needle misplacement and complications
9. Inadequate mastering of Dutch language. When patients are unable to communicate with the primary researcher or fill in the questionnaires, it is not possible to assess their progress or receive informed consent.
10. Allergy to corticosteroids
11. Women who are pregnant, have an active pregnancy wish or are lactating
12. Incapacity of will

Date of first enrolment
01/09/2005

Date of final enrolment
01/09/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
P.O. Box 196
Groningen
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9700 AD

Sponsor information

Organisation
University Medical Centre Groningen (UMCG) (The Netherlands)

Sponsor details
Department of General Practice
Hanzeplein 1
Groningen
Netherlands
9713 GZ

Sponsor type
Hospital/treatment centre

Website
http://www.umcg.nl/azg/nl/

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Medical Centre Groningen (UMCG) (The Netherlands) - doelmatigheidsbureau (MTA)

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