SLURP: Steroidinjections in LUmbosacral Radicular Syndrome.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23550

Source
NTR

Brief title
SLURP

Health condition

Lumbosacral Radicular Syndrome, pain radiating from the back to the leg, to below the knee, due to irritated nerve roots. In most cases, the cause is a protruding low lumbar disc.

Sponsors and support

Primary sponsor: MTA (doelmatigheidsbureau) UMCG.
Department of General Practice, University of Groningen.
Source(s) of monetary or material Support: MTA (doelmatigheidsbureau) UMCG.

Intervention

Outcome measures

Primary outcome

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

1. Mobility, which the Roland-Morris disability questionnaire;
2. Quality of life, measured with SF36;
3. Primary and secondary health care costs.

Study description

Background summary

INTRODUCTION:
Lumbosacral radicular syndrome (LRS) is defined according to the Guidelines of the Dutch College of General Practitioners (GPs) as pain, radiating from the back into the leg to below the knee, in combination with either Lasï¿½gueï¿½s sign, or with segmental disorder characterized by paresis, sensory disorders and/or changes in reflexes reducible to a single nerve root. It is most commonly caused by protrusion of a low lumbar intevertebral disc. The average Dutch GP encounters ten to twelve patients with LRS per year. Because of the pain and inability to work, LRS is troublesome for the patient and places a great financial burden on our healthcare system. Many patients with LRS do not respond satisfactory to the usual conservative treatment, which consists of pain medication and bedrest, followed by mobilisation with avoidance of painful movements. Although segmental epidural steroid injections (SESIs) are not considered an evidence-based therapeutic option in the treatment of LRS, evidence exists that SESI may be a helpful intervention, especially when administered in the acute phase. The question remains whether this is a cost-effective and general practice applicable strategy.

RESEARCH QUESTION:
Is administration of one or two SESIs on top of standard treatment a cost-effective, general practice applicable intervention in the acute phase of LRS when patients do not satisfactory respond to conservative treatment?

METHODOLOGY:
A randomized controlled general practice trial comparing additional segmental epidural steroid injections to care as usual in patients suffering from acute lumbosacral radicular syndrome. Patients who respond unsatisfactory to conservative treatment for LRS are referred by their GPs to the anesthesiology outpatient clinic of the University Medical Centre Groningen and will be randomly assigned to either the control group or the intervention group. Intervention treatment consists of care as usual and an additional segmental epidural corticosteroid injections containing 80 mgs of triamcinolone-acetonide, once repeated if necessary. The control group receives care as usual. The treatment according to the Dutch College of General Practitionersï¿½ Guideline on LRS consists of analgesics, mobilisation with avoidance of painful movements and/or referral to a neurologist. Follow-up will be at 2, 4 and

6 weeks, 3 months, 6 months and 1 year after the intervention. Primary outcome measures are: pain in back and/or leg while walking, standing and lying down, severity of main complaint, perceived recovery and satisfaction with treatment. Secondary outcome measures are: primary and secondary healthcare costs, mobility and quality of life. To demonstrate a clinically significant difference of 35 points with a standard deviation of 17 on a numerical rating scale, given a statistical power of 80% and an alpha of 5%, we will need to include 30 patients in each group. Our aim is to include a total number of 80 patients to take lost-to-follow-up into account.

Study objective

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

Intervention

Intervention group: Care as usual, combined with one or two segmental epidural corticosteroid injections (80 mg kenacort);
Control group: Care as usual.

Contacts

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Eligibility criteria

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.

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 patientsï¿½ 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 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: BMI (weight/square length) > 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2005
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL304
NTR-old	NTR342
Other	: 1705
ISRCTN	ISRCTN54386944

Study results

Summary results
N/A