

SLURP: Steroidinjections in Lumbosacral Radicular Syndrome.

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23550

Bron

NTR

Verkorte titel

SLURP

Aandoening

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.

Ondersteuning

Primaire sponsor: MTA (doelmatigheidsbureau) UMCG.

Department of General Practice, University of Groningen.

Overige ondersteuning: MTA (doelmatigheidsbureau) UMCG.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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 Lasegue's 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 intervertebral 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 (SEIs) are not considered an evidence-based therapeutic option in the treatment of LRS, evidence exists that SEI 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 SEIs 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 Practitioners' 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.

Doel van het onderzoek

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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' L_4/L_5 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 acetylsalicylic 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 too 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blinding:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2005
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	19-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register

NTR-new

NTR-old

Ander register

ISRCTN

ID

NL304

NTR342

: 1705

ISRCTN54386944

Resultaten

Samenvatting resultaten

N/A