

Conservative treatment in patients with an acute Lumbosacral Radicular Syndrome: design of a randomised clinical trial

Submission date
01/11/2004

Recruitment status
No longer recruiting

☐ Prospectively registered

☒ Protocol

Registration date
01/11/2004

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
19/08/2009

Condition category
Musculoskeletal Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Study information

Scientific Title

Acronym

LRS trial

Study objectives

Added 19/08/09:

The aim of this study is to determine effectiveness of physical therapy added to general practitioners management compared to general practitioners management only in patients with an acute lumbosacral radicular syndrome (also called sciatica).

As of 19/08/09 this record has been extensively updated. All updates can be found under the relevant field with the above update date.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 19/08/09: Received from Erasmus Medical Centre Ethics Committee

Primary study design

Interventional

Study design

Randomised open label active controlled parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Lumbosacral Radicular Syndrome also called sciatica

Interventions

Physical therapy added to general practitioners management compared to general practitioners management only.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Added 19/08/09:

Global Perceived Effect (GPE) - measured on a 7 points scale ranging from 1 = completely recovered to 7 = vastly worsened

Key secondary outcome(s)

Added 19/08/09:

1. Pain severity of the leg and the back - scored on a 11 points Visual Analogue Scale (VAS) ranging from 0 = no pain to 10 = unbearable pain
2. Functional status - measured with the Roland Morris Disability Questionnaire (RDQ) for sciatica. The scoring of the RDQ is achieved by counting the number of positive responses: a patient individual score can vary from 0 (no disability) to 24 (severe disability)
3. Health status - measured by the 36-item short form (SF-36) and the Euroqol (EQ-5D) instrument

4. Fear of movement - measured by the Tampa scale for kinesiophobia (TSK)
5. Costs will be calculated and include
 - 5.1. LRS related sickness absence from work,
 - 5.2. Medical consumption (i.e. medication use, additional therapies, visits to health care providers)
 - 5.3. Out-of-pocket expenses
 - 5.4. Paid help
6. Patients' treatment preference - evaluated at baseline and at 4 follow-up measurements.

Completion date

01/11/2004

Eligibility

Key inclusion criteria

1. Radiating (pain) complaints in the leg below the knee
2. Severity of complaints scored above 3 on a 10 point Visual Analogue Scale (VAS) (0 = no complaints; 10 = maximum complaints)
3. Duration of the (pain) complaints less than 6 weeks
4. Age above 18 years
5. Able to speak and read Dutch
6. Presents of one of the following symptoms:
 - 6.1. More pain on coughing, sneezing or straining
 - 6.2. Decreased muscle strength in the leg
 - 6.3. Sensory deficits in the leg
 - 6.4. Decreased reflex activity in the leg
 - 6.5. Positive straight leg raising test

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Radiating (pain) complaints in the preceding 6 months
2. Back surgery in the past 3 years
3. Treated with epidural injections
4. Pregnancy
5. Co-morbidity that primary determines overall well being
6. Direct indication for surgery (unbearable pain, fast progression of paresis or cauda equina)

syndrome

7. Expected loss to follow-up (i.e. moving towards other part of the country, long lasting foreign holiday)

Date of first enrolment

01/05/2003

Date of final enrolment

01/11/2004

Locations

Countries of recruitment

Netherlands

Study participating centre

P.O. Box 1738

Rotterdam

Netherlands

3000 DR

Sponsor information

Organisation

Erasmus Medical Centre (Netherlands)

ROR

<https://ror.org/018906e22>

Funder(s)

Funder type

Government

Funder Name

Dutch Health Care Insurance Board (College voor Zorgverzekeringen) (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/08/2007		Yes	No
Protocol article	protocol	09/11/2004		Yes	No