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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

Registration date
01/11/2004

Overall study status
Completed

Last Edited
19/08/2009

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
N/A

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 relavent 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

Study design
Randomised open label active controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

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 measure
Added 19/08/09:
Global Perceived Effect (GPE) - measured on a 7 points scale ranging from 1 = completely recovered to 7 = vastly worsened

Secondary outcome measures
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.

Overall study start date
01/05/2003

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Added 22/04/2008: 135 patients randomised

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
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Sponsor information

Organisation
Erasmus Medical Centre (Netherlands)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Government

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

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

Study outputs

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