ISRCTN25018352 https://doi.org/10.1186/ISRCTN25018352

Physiotherapy for Sciatica: Is Earlier Better?

Submission date
10/12/2015

Recruitment status
No longer recruiting

Registration date
10/12/2015

Overall study status
Completed

Last Edited
25/04/2019

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Sciatica is the name given to pain in the lower back or legs, caused by the compression (squeezing) or irritation of the sciatic nerve. The sciatic nerve is the longest nerve in the body, running from the spine at the level of the lower back through the hips and buttocks and down each leg. One of the most common causes causes of sciatica occurs when the sciatic nerve is compressed (squashed) or irritated by one of the discs which separate the bones in the spine (vertebrae) sticking out (herniating). Typically, most people only experience sciatica on one side of the body, and the pain can range from mild to so severe that it is physically disabling. In most people, the condition can improve on its own however physiotherapy is widely used in order to speed up recovery. A Physiotherapist is able to help devise a management programme with the patient in order to improve function, help pain management and optimise the bodys' natural healing response. The length of time between referral from the GP and physiotherapy can vary greatly in different parts of the UK however this is thought to be because of local clinical commissioning group decisions rather than medical recommendations. The aim of this study is to compare the benefits of early physiotherapy (within 2 weeks of referral) to the standard wait time (of around 6 weeks) in the treatment of patients with sciatica. The study also aims to find out whether it would be possible to conduct a larger trial in the future.

Who can participate?
Adults between 18 and 70 years old with sciatica in one leg.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group are referred to see a physiotherapist within 2 weeks of seeing their GP. Each participant is interviewed by the physiotherapist and their physiotherapy regimen is tailored to their individual needs. Participants in the second group a referred to see a physiotherapist around 6 weeks after seeing their GP, as is usual practice. After 6 months, participants in both groups are interviewed in order to find out whether they feel that they have reached the goals that they set in the initial meeting with the physiotherapist. The amount of participants that took part and how many continued to the end of the study is then recorded, so that the investigators can decide whether a larger study would be appropriate.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Northern General Hospital (UK)

When is the study starting and how long is it expected to run for?
February 2016 to August 2017

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Mr Michael Reddington

Contact information

Type(s)
Public

Contact name
Mr Michael Reddington

ORCID ID
http://orcid.org/0000-0001-8139-2103

Contact details
School of Health and Related Research
Regents Court
30 Regent Street
Sheffield
United Kingdom
S1 4DA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02618278

Secondary identifying numbers
19794

Study information

Scientific Title
Physiotherapy management Of LumbAr Radicular syndrome: does early intervention improve outc

Acronym

POLAR

Study objectives
The aim of this study to investigate the effects of early intervention physiotherapy for people with sciatica, and to determine the feasibility of performing a full-scale trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of Scotland Research Ethics Service, 20/08/2015, ref: 15/ES/0130

Study design
Mixed methods randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Musculoskeletal disorders; Subtopic: Musculoskeletal (all Subtopics); Disease: Musculoskeletal

Interventions
Participants are randomly allocated to one of two groups.

Group 1: Participants receive an individual, goal-orientated physiotherapy management package within 2 weeks G.P referral for physiotherapy.

Group 2: Participants receive the same individual, goal-orientated physiotherapy management as the intervention arm but at 6 weeks post G.P referral, as is usual care.

Participants in both groups are followed up at 6 months post-randomisation.

Intervention Type
Other

Primary outcome measure

1. Recruitment rate is determined at 26 weeks
2. Attrition rate is determined at 26 weeks

Secondary outcome measures
1. Feasibility measures for a future, full-scale trial include attrition rates, recruitment rate, acceptability of the intervention to patient and clinician, patient adherence to the intervention and will be measured with monthly report and analysis
2. Oswestry Disability Index will be used to assess self-rated disability at baseline, 6 weeks, 12 weeks and 26 weeks
3. Pain will be measured using the VAS pain scale for back and leg pain at baseline, 6 weeks, 12 weeks and 26 weeks
4. General health status will be measured using the EQ5D-5L tool at baseline, 6 weeks, 12 weeks and 26 weeks

Overall study start date
01/02/2016

Completion date
01/02/2018

Eligibility

Key inclusion criteria
1. Aged between 18 and 70 years of age
2. Presence of unilateral lumbar radicular syndrome (defined as pain and or sensory disturbance and or weakness in a dermatomal and/or myotmal distribution)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 80; UK Sample Size: 80; Description: 80 patients will be recruited from primary care G.P practices and randomised into 2 groups.

Total final enrolment
80

Key exclusion criteria
1. Bilateral lumbar radicular syndrome (LRS)
2. Patients with ‘red flag’ signs and symptoms of potential serious pathology

3. Cancer at the time of the study
4. Proven vascular claudication
5. Cauda Equina Syndrome (CES)
6. Spinal fracture within the last 3 months
7. Chronic regional pain syndromes
8. Recent lower limb fracture
9. CVA with physical and/or psychiatric disability
10. Poor English skills (necessitating the use of an interpreter and invalidating outcomes measures--ODI as well as increasing costs)
11. Other significant co-morbidities preventing regular attendance at physiotherapy clinics
12. Patients with significant mental health problems for which treatment adherence may be difficult or psychologically disabling (at the discretion of the referring G.P)

Date of first enrolment
01/02/2016

Date of final enrolment
06/11/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Northern General Hospital
South Yorkshire Cardiothoracic Unit
Sheffield Teaching Hospitals NHS Trust
Herries Road
Sheffield
United Kingdom
S5 7AU

Sponsor information

Organisation
Northern General Hospital

Sponsor details
South Yorkshire Cardiothoracic Unit
Sheffield Teaching Hospitals NHS Trust
Herries Road
Sheffield
England

United Kingdom
S5 7AU

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05r409z22

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication of study results in a peer reviewed journal, as well as presentation at relevant conferences.

Intention to publish date
31/07/2017

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	03/03/2017		Yes	No
Results article	results	28/07/2018	25/04/2019	Yes	No
HRA research summary			26/07/2023	No	No