

Physiotherapy for Sciatica: Is Earlier Better?

Submission date 10/12/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 10/12/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/04/2019	Condition category Musculoskeletal Diseases	<input type="checkbox"/> 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 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 body's 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 are 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
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S1 4DA

Additional identifiers

ClinicalTrials.gov (NCT)
NCT02618278

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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 myotomal distribution)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

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

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

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