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Assessment and Treatment of Leg pain Associated with the Spine (ATLAS)

Submission date
22/06/2011

Recruitment status
No longer recruiting

Registration date
13/09/2011

Overall study status
Completed

Last Edited
12/12/2018

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Patients with back pain may or may not experience pain which spreads to their legs. Previous research has found that patients who have back and leg pain suffer more severe pain and disability, take longer to recover, and lose more time off work than those with back pain alone. However, it is not known if this is because of the leg pain or some other related factor(s).
One type of leg pain, called Nerve Root Pain, often spreads below the knee and means there is a problem with the nerves. Doctors think it is important to distinguish between patients who have back pain alone, those with back and leg pain, and those with back pain and nerve root pain. This is so that these groups can be assessed and treated appropriately.
The study aims to answer the following research questions: what are the characteristics and costs of patients with back and leg pain at the time they consult their GP and over the following 12 months, and which factors are associated with a worse outcome? Do patients with nerve root pain differ from those with no nerve root pain?

Who can participate?
Patients with lower leg and back pain.

What does the study involve?
Patients who consult their GP for back and leg pain will be referred to a community clinic for assessment by a physiotherapist and treatment according to their symptoms. Five hundred patients will be recruited to the study. Information about the characteristics (pain, disability, psychological factors, employment, other health conditions, health care use) of these patients will be collected on postal questionnaires at baseline (when they are enrolled in the study), and each month for the following year. Participants will also have a Magnetic Resonance Imaging (MRI) scan at baseline.

What are the possible benefits and risks of participating?
This study will inform better targeting of treatment to improve outcomes in patients with back and leg pain, which will be tested in future trials.
There are no risks to participants from taking part in this study.

Where is the study run from?
The study is taking place in North Staffordshire and Stoke-on-Trent (UK).

When is the study starting and how long is it expected to run for?
The study started in March 2011 and is expected to complete in December 2013.

Who is funding the study?
The National Institute for Health Research (NIHR), UK.

Who is the main contact?
Dr Kika Konstantinou (Principal Investigator)

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
9961

Study information

Scientific Title
Clinical course, characteristics and prognostic indicators in patients presenting with back and leg pain in primary care

Acronym
ATLAS

Study objectives
Patients with back pain may or may not experience pain which spreads to their legs. Previous research has found that patients who have back and leg pain suffer more severe pain and disability, take longer to recover, and lose more time off work than those with back pain alone. However, it is not known if this is because of the leg pain or some other related factors. One type of leg pain, called Nerve Root Pain, often spreads below the knee and means there is a problem with the nerves. Doctors think it is important to distinguish between patients who have

back pain alone, those with back and leg pain, and those with back pain and nerve root pain. This is so that these groups can be assessed and treated appropriately.

Research questions:
1. What are the characteristics and costs of patients with back and leg pain at the time they consult their GP and over the following 12 months, and which factors are associated with a worse outcome?
2. Do patients with nerve root pain differ from those with no nerve root pain?
3. Patients who consult their GP for back and leg pain will be referred to a community clinic for assessment by a physiotherapist and treatment according to their symptoms.

Five hundred patients will be recruited to the study. Information about the characteristics (pain, disability, psychological factors, employment, other health conditions, health care use) of these patients will be collected on postal questionnaires at baseline, and during one year of followup. Participants will also have an MRI scan at baseline. This study will inform better targeting of treatment to improve outcomes in patients with back and leg pain, which will be tested in future trials.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Birmingham Research Ethics Comittee, 19/10/2009, ref: 10/H1207/82

Primary study design
Observational

Study design
Non-randomised observational cohort study

Study type(s)
Screening

Health condition(s) or problem(s) studied
Musculoskeletal diseases

Interventions
1. Patients receive a standardised physiotherapy assessment for back and leg pain and are treated by a study physiotherapist according to need
2. Clinical management will follow agreed care pathways, based on current best clinical evidence, practice guidelines and local services and resources
3. Allocation to one of 3 care pathways will take into account the patients diagnosis, severity of symptoms, response to previous treatment, and patient preferences

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)

Disability - Roland and Morris Disability Questionnaire (RMDQ, leg pain version) measured at baseline, 4 month and 12 months

Key secondary outcome(s)
1. Co-morbidity measured at baseline
2. Employment status, work absence, sick certification and difficulties at work measured at baseline, 4 months and 12 months
3. Episode Duration - current episode for each back and leg pain, plus time since pain free month measured at baseline and 12 months
4. General Health (SF1 and EQ5D) measured at baseline, 4 month and 12 month
5. Global assessment of change 0-10 numerical rating scale measured at 4 months and 12 months
6. Health care utilisation measured at 4 months and 12 months
7. Height and Weight measured at baseline
8. Hospital Anxiety and Depression Scale (HADS) measured at baseline and 12 months
9. Illness Perceptions (Musculoskeletal IPQ-R Short Form) measured at baseline, 4 months and 12 months
10. Neuropathic pain (S-LANSS) measured at baseline, 4 month and 12 months
11. Pain intensity (current, average and 'least' pain in the last 2 weeks for both back and leg pain measured at baseline, 4 months and 12 months
12. Pain Location measured at baseline and 12 months
13. Pain Self Efficacy Questionnaire (PSEQ) measured at baseline, 4 months and 12 months
14. Pain trajectory measured at baseline and 12 months
15. Productivity - Performance at work single numerical rating scale measured at baseline, 4 months and 12 months
16. Risk of poor outcome (STarT Back tool) measured at baseline, 4 months and 12 months
17. Satisfaction with care measured at 4 months
18. Sciatica Bothersomeness Index (SBI) measured at baseline, 4 months and 12 months
19. Smoking measured at baseline
20. Work Load measured at baseline

Completion date
01/01/2012

Eligibility

Key inclusion criteria
1. Adults aged 18 years and over consulting their GP with LBP and radiating leg pain of any duration
2. Male or female
3. Lower Age Limit 18, no upper age limit

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 Years

Sex
All

Key exclusion criteria
1. Persons with red flags indicative of possible serious spinal pathology
2. Serious co-morbidity which stop patients from being able to undergo the assessment
3. Patients with serious mental health problems who are vulnerable and for whom participation in the study would be detrimental (at the GPs discretion)
4. Previous spinal surgery
5. Pregnancy
6. Currently receiving physiotherapy (or osteopathy, chiropractic) or under a secondary care consultant for the same problem
7. Not able to read and speak English

Date of first enrolment
01/01/2011

Date of final enrolment
01/01/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Arthritis Research UK Primary Care Centre
Newcastle Under Lyme
United Kingdom
ST5 5BG

Sponsor information

Organisation
Keele University (UK)

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research ref: RP-PG-0707-10131

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	04/11/2015		Yes	No
Results article	results	01/06/2018		Yes	No
Protocol article	protocol	20/01/2012		Yes	No