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Clinical course and prognostic indicators in patients presenting with back and leg pain in primary care

Submission date
02/04/2014

Recruitment status
No longer recruiting

Registration date
06/05/2014

Overall study status
Completed

Last Edited
07/09/2020

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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 factors. One type of leg pain, called 'Nerve Root Pain', often spreads below the knee and means there is a problem with the nerves in the spine. 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 ATLAS cohort study aimed to describe over one year the clinical course, characteristics and factors that predict the outcome for patients with back and leg pain including sciatica. The aim of this study is to conduct longer term follow-ups (at 3, 4 and 5 years) of this established group in order to describe over a longer time frame the clinical course, characteristics, factors that predict outcome and healthcare use over time, including direct and indirect healthcare costs. Similarities and/or differences of those factors are also investigated at the different time points to find out what predicts short-term and long-term outcomes. This knowledge will inform better targeting of treatment to improve outcomes in patients with back and leg pain, which will be tested in future studies.

Who can participate?
Patients who took part in the ATLAS study

What does the study involve?
ATLAS participants (apart from those who withdrew from the study or declined further contact for research purposes at their 12-month questionnaire) are sent a letter introducing the new longer term follow-up study 2 weeks before the third anniversary of their first ATLAS assessment visit, followed by further information and the study questionnaire 2 weeks later. Participants who respond to this questionnaire are then sent two further questionnaires at 4

and 5 years, respectively. Participants are also asked to give permission for the researchers to review their medical records to assess GP visits, medication and hospital visits in order to measure their healthcare use.

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

Where is the study run from?
University of Keele (UK)

When is the study starting and how long is it expected to run for?
April 2014 to June 2018

Who is funding the study?
Arthritis Research UK (UK)

Who is the main contact?
Ms Jacqueline Gray

Contact information

Type(s)
Scientific

Contact name
Ms Jacqueline Gray

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Additional identifiers

Protocol serial number
16279

Study information

Scientific Title
Clinical course and prognostic indicators in patients presenting with back and leg pain in primary care: 3, 4 and 5 year prospective study (ATLAS study cohort)

Acronym
ATLAS follow-up study

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 in the spine. 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 ATLAS cohort observational study aims to describe over one year the clinical course, characteristics and factors that predict outcome in patients consulting in primary care with back and leg pain including sciatica. The aim is to conduct longer term follow-ups (at 3, 4 and 5 years) of this established cohort in order to describe over a longer time frame the clinical course, characteristics, factors that predict outcome and health care utilisation over time, including direct and indirect health care costs. Similarities and/or differences of those factors will also investigated at the different time points to characterise better what predicts short-term and long-term outcomes. This knowledge 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)
MREC, 08/01/2014, 13/NS/0170

Primary study design
Observational

Study design
Non-randomised; Observational; Design type: Cohort study

Study type(s)
Treatment

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

Interventions
The ATLAS study looked at how people who visit their GP with back and leg pain do over time. This follow-up study aims to follow the same group of people at 3, 4 and 5 years after their initial participation in the ATLAS study to understand why some people take longer periods of time to recover than others. This information will be used to develop ways to improve the care of people with back and leg pain.

The aim is to conduct longer term follow-ups (at 3, 4 and 5 years) of the established ATLAS cohort in order to describe over a longer timeframe the clinical course, characteristics, prognostic indicators and health care utilisation over time, including direct and indirect health care costs. Similarities and/or differences of prognostic indicators will also investigated at the different time points.

At baseline ATLAS (REC reference: 10/H1207/82) participants attended an initial assessment clinic visit followed by treatment as appropriate, and were then followed up by questionnaire

for 12 months. In this proposed study of longer term follow-up of the ATLAS cohort, ATLAS participants (with the exception of those who withdrew from the study or declined further contact for research purposes at their 12-month questionnaire) will be approached. Potential participants will be sent a letter introducing the new longer term follow-up study 2 weeks before the third anniversary of their baseline ATLAS assessment visit, followed by further information and the study questionnaire 2 weeks later. Participants who respond to this questionnaire will then be sent two further questionnaires at 4 and 5 years, respectively. Participants will also be asked to give permission for medical record review to capture GP visits and medication for the same problem and secondary care/hospital visits (inpatient and outpatient) in order to describe health care used over time by this cohort.

Study Entry: Registration only

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Improvement in the RMDQ (Roland and Morris Disability Questionnaire using the leg pain version): defined as a change of at least 30% improvement in an individual's RMDQ score (Jordan et al., 2006). This will be measured at 3, 4 and 5 years.

Key secondary outcome(s)
N/A

Completion date
30/06/2018

Eligibility

Key inclusion criteria
1. Previous participants in the ATLAS study
2. Target Gender: Male & Female

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria

1. Withdrawn or excluded from the ATLAS study
2. Declined further contact for research purposes at their 12-month follow-up questionnaire

Date of first enrolment
02/04/2014

Date of final enrolment
30/06/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Keele University
Newcastle-Under-Lyme
United Kingdom
ST5 5BG

Sponsor information

Organisation
University of Keele (UK)

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research UK (UK)

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype
Other non-profit organizations

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?
Protocol article	protocol	20/01/2012	07/09/2020	Yes	No
HRA research summary			28/06/2023	No	No