

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 06/05/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 07/09/2020	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Contact details
Arthritis Research UK Primary Care Centre
Primary Care Sciences
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 be 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

Study design

Non-randomised; Observational; Design type: Cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

GP practice

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

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 be 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 measure

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.

Secondary outcome measures

N/A

Overall study start date

02/04/2014

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

Age group

Adult

Sex

Both

Target number of participants

Planned Sample Size: 300; UK Sample Size: 300

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

England

United Kingdom

Study participating centre

Keele University

Newcastle-Under-Lyme

United Kingdom

ST5 5BG

Sponsor information

Organisation

University of Keele (UK)

Sponsor details

Keele
Newcastle
England
United Kingdom
ST5 5BG

Sponsor type

University/education

Website

<http://www.keele.ac.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**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	20/01/2012	07/09/2020	Yes	No
HRA research summary			28/06/2023	No	No