

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

<b>Submission date</b> 22/06/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 13/09/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/12/2018	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> 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

Ms Jacqueline Gray

### Contact details

Arthritis Research UK Primary Care Centre

Primary Care Sciences

Keele University

Staffordshire

Newcastle Under Lyme

United Kingdom

ST5 5BG

## 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 Committee, 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?
<a href="#">Results article</a>	results	04/11/2015		Yes	No
<a href="#">Results article</a>	results	01/06/2018		Yes	No
<a href="#">Protocol article</a>	protocol	20/01/2012		Yes	No