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The influence of cytokine biomarkers on sciatica

Submission date	Recruitment status	[_] Prospectively registered
23/08/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/10/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/07/2018	Musculoskeletal Diseases	

Plain English summary of protocol

Background and study aims:
The aim of this study is to try and identify whether chemicals in the blood called cytokines influence pain in people with sciatica. We will examine the blood samples and investigate the presence of such chemicals. We will also investigate whether the presence of any of these chemicals is related to higher pain levels. Through this study we hope to improve our understanding of sciatica and how it might be treated.

Who can participate?
This study takes place within a larger study (ATLAS) and patients for this study will be recruited from the ATLAS study. These participants will be adults aged 18 years and over who are attending an ATLAS clinic because they have consulted their GP with low back and leg pain of any duration and who consent and are eligible to take part in the ATLAS study.

What does the study involve?
Patients will attend a phlebotomy service, where a 10ml blood sample will be collected by an experienced hospital phlebotomist. Only one sample will be collected, on a single occasion.

What are the possible benefits and risks of participating?
There is not expected to be any benefit to patients who take part in the research study. The data generated from this study will help to extend our understanding of the role of inflammation in sciatica. This may ultimately have implications for improved treatment strategies and care in the future, although not necessarily for the participants of the study.
As a blood sample will be taken there is the potential risk of experiencing discomfort.

Where is the study run from?
The Arthritis Research UK Primary Care Centre at Keele University, UK

When is study starting and how long is it expected to run for?
The study started on 07 June 2012, and is expected to run for 10 months.

Who is funding the study?
Department of Health - Academic Training Programme for Nurses, Midwives and Allied Health Professionals

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
Ms Jacqueline Gray

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12681

Study information

Scientific Title
The Influence of cytokine biomarkers on sciatica: a nested study within the ATLAS cohort

Study objectives
Sciatica describes the clinical syndrome of leg pain and or weakness, which is usually caused by irritation of the sciatic nerve. Studies show that patients with sciatica suffer more severe pain and disability, take longer to recover, and lose more time off work than those with back pain alone. Studies suggest inflammation may be a key cause of sciatica and specific medicines called cytokine inhibitors have been shown to give promising results for the treatment of sciatica. These therapies may represent a novel way of treating sciatica but are expensive. Data is required to effectively target these drugs at patients most likely to derive benefit. This study will compare blood levels of cytokines in patients with recent onset sciatica symptoms to patients with non specific low back pain. The study will also determine whether the levels are

linked to clinical factors such as pain intensity, severity or disability. Patients will be recruited from clinics of an existing low back and leg pain cohort study (ATLAS study). Patients agreeing to take part will be asked to give a single blood sample for the research.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Comittee North West - Greater Manchester South, 10 April 2012, ref: 12/NW/0173

Study design
Non-randomised observational study

Primary study design
Observational

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Sciatica

Interventions
We aim to recruit 120 participants from patients attending ATLAS clinics. As part of the ATLAS clinic, the patients are assessed by a physiotherapist who will determine if they have a radiculopathy (sciatica due to disc herniation) or non specific low back and leg pain (NSLBLP). At the ATLAS study clinics we aim to recruit 80 patients with radiculopathy symptoms and 40 patients with NSLBLP. Following the results of the MRI scan we plan to subdivide the radiculopathy patients into those with and without disc herniation on MRI, which is expected to produce three groups
1. 40 patients with radiculopathy symptoms and disc herniation on MRI
2. 40 patients with radiculopathy symptoms and no disc herniation on MRI
3. 40 patients with nonspecific low back pain

Following collection the blood samples will be centrifuged and plasma will be separated from blood within an hour of collection and stored at 80°C at the Haywood Hospital. Plasma cytokine and MMP levels will be measured using commercial multiplex detection kits (BioRad & R&D Systems).

Simple comparisons between biomarker levels will be performed using MannWhitney U tests. Data will also be analysed using software designed for microarray analysis (e.g. GENESIS) using hierarchical clustering and principal component analysis.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Median cytokine levels compared across the 3 study groups measured at baseline

Secondary outcome measures
1. Comparing cytokine levels with baseline
2. Pain intensity, pain severity and pain duration measured at baseline

Overall study start date
07/06/2012

Completion date
29/03/2013

Eligibility

Key inclusion criteria
This study is nested within a larger cohort study (ATLAS study) and patients for this study will be recruited from the ATLAS cohort.

Hence the principal inclusion criteria is:
1. Adults aged 18 years and over who are attending an ATLAS clinic because they have consulted their GP with low back
2. Leg pain of any duration and who consent and are eligible to take part in the ATLAS study
3. Male & female participants

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
UK Sample Size: 120

Key exclusion criteria
Ineligibility and/or not consenting to take part in the ATLAS study. All participants for this study will be recruited from the ATLAS study hence the exclusion criteria to take part in this study are the same as the exclusion criteria for the ATLAS study:
1. Persons with signs and symptoms indicative of possible serious spinal pathology
2. Serious comorbidity 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
07/06/2012

Date of final enrolment
29/03/2013

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
Keele University (UK)

Sponsor details
Keele Road
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Sponsor type
University/education

Website
http://www.keele.ac.uk/

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Government

Funder Name
Department of Health (UK)

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?
Abstract results	results presented at EULAR	01/06/2015		No	No