ISRCTN18170726 https://doi.org/10.1186/ISRCTN18170726

Factors predicting the transition from acute to persistent pain in people with 'sciatica'-the FORECAST longitudinal prognostic factor cohort

Submission date
30/01/2023

Recruitment status
No longer recruiting

Registration date
10/02/2023

Overall study status
Completed

Last Edited
14/10/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Sciatica is very common and is caused by injured or irritated nerves in the lower back. Sciatica causes pain, tingling or weakness in the leg. It can have a devastating effect on everyday life. For instance, patients cannot complete their normal work or care for their families. Sadly, about one in three patients develops persistent sciatica pain. We currently do not understand why some patients develop persistent pain and why some recover. Previous research has demonstrated that usual clinical findings (e.g., depression or routine MRI) cannot predict persistent sciatica. A different approach is therefore needed to identify who may develop persistent sciatica. This is the goal of the FORECAST study.

FORECAST is performed by a team of medical doctors, neuroscientists, statisticians, and MRI specialists at Oxford University. The team also includes patient partners who help us design and run our study. Our FORECAST study is different to previous studies. Whereas previous studies only included a short clinical examination, we will perform a detailed set of tests. We hope that the detailed tests can predict who develops persistent pain. The questions we hope to answer in the FORECAST study comprise whether the detailed tests identify different subgroups of patients with sciatica and which of these detailed tests predict pain persistence. The FORECAST study is a substudy of the PiPL platform. PiPL aims to understand prognostic factors for pain persistence and the nature of nerve-related pain in patients with different peripheral nerve injuries and includes many different substudies in different patient populations.

Who can participate?
Adults with recent onset of sciatica (symptoms<3 months)

What does the study involve?
The FORECAST study is a substudy of the PiPL study (IRAS 241777). In the first assessment, the team will perform detailed tests. This includes detailed sensory nerve testing (quantitative sensory testing) and a precise set of questionnaires to evaluate the type of pain and emotional well-being. A blood sample will also be taken to look for signs of inflammation. Some patients will receive specialised magnetic resonance imaging to evaluate the microscopic structure of the

small nerves in the back. These images are much more detailed and specialised than routine MRI scans. Patients will be contacted again three months and one year later, to ask whether they still have sciatica symptoms. Statistics will be used to identify patient subgroups and to find out which tests predict pain persistence.

What are the possible benefits and risks of participating?
There is no direct benefit to participants, but the information we get might help improve the treatment of people with sciatica in the future.
There are no particular risks to this study. MRI is considered a safe procedure, and we will only invite people with no contraindications to MRI for scanning.

The results of the FORECAST study will help us better understand the complexity of sciatica and who develops persistent pain. The findings will also help future research. For instance, future studies can examine whether giving more specific treatment to patients who are likely to develop persistent pain can reduce chronic pain. It is hoped that the results of the FORECAST study will help reduce suffering and improve the quality of life for patients with sciatica.

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

When is the study starting and how long is it expected to run for?
The PiPL platform study commenced in January 2018 and the FORECAST substudy runs from May 2021 to September 2025

Who is funding the study?
1. UK Research and Innovation (UK)
2. Versus Arthritis (UK)
3. National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Prof Annina Schmid, annina.schmid@ndcn.ox.ac.uk (UK)

Contact information

Type(s)
Principal investigator

Contact name
Prof Annina Schmid

ORCID ID
https://orcid.org/0000-0001-7759-0211

Contact details
Nuffield Department of Clinical Neurosciences
John Radcliffe Hospital
West Wing Level 6
Oxford
United Kingdom

OX3 9DU
+44 (0)1865 223254
annina.schmid@ndcn.ox.ac.uk

Type(s)
Scientific

Contact name
Prof Annina Schmid

Contact details
Nuffield Department of Clinical Neurosciences
John Radcliffe Hospital
West Wing Level 6
Oxford
United Kingdom
OX3 9DU
+44 (0)1865 223254
annina.schmid@ndcn.ox.ac.uk

Type(s)
Public

Contact name
Prof Annina Schmid

Contact details
Nuffield Department of Clinical Neurosciences
John Radcliffe Hospital
West Wing Level 6
Oxford
United Kingdom
OX3 9DU
+44 (0)1865 223254
annina.schmid@ndcn.ox.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
FactORs prEdiCting the trAnsition from acute to persistent pain in people with ‘SciaTica’-the FORECAST longitudinal prognostic factor cohort, a substudy of the PiPL platform

Acronym
FORECAST

Study objectives
The FORECAST study is a substudy of the PiPL platform study (IRAS 241777).

The aims of the FORECAST study are:
1. To explore mechanism-based subgroups in patients with acute/subacute sciatica
2. To investigate whether a mechanism-based approach can identify factors that predict pain persistence in people with sciatica

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/05/2018, South Central - Oxford C Research Ethics Committee (Level 3, Block B, Whitefriars Building, Lewis Mead, Bristol, BS12NT, UK; +44 (0)207 1048289; oxfordc.rec@hra.nhs.uk), ref: 18/SC/0263

Study design
Single-centre prospective longitudinal prognostic factor cohort study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Acute/subacute sciatica/low back pain

Interventions
The FORECAST study is a prospective longitudinal prognostic factor cohort study involving patients with acute/subacute 'sciatica' and healthy age- and gender-matched participants without symptoms of sciatica/low back pain. The study is based on feasibility data and closely informed by patient and public involvement and engagement (PPIE) activities including feedback from our named patient partners, a six-member patient advisory group, and survey results from participants of the feasibility study. The study will be performed and reported according to the guidelines for observational studies (STROBE) and the statement for transparent reporting of a multivariable prediction model for individual prognosis or diagnosis (TRIPOD).

The study will include patients with acute/subacute 'sciatica' and healthy age- and gender-matched participants without symptoms of sciatica/low back pain. Healthy participants are essential to establish normative values for blood markers, somatosensory profiling and neuroimaging.

After a preliminary eligibility screen on the telephone, patients will attend a baseline appointment with a clinically trained investigator (e.g, physiotherapist) at the local University Department. During the baseline appointment, the diagnosis of sciatica will be confirmed, and the prognostic variables will be assessed through a detailed set of clinical phenotyping as described below. Some patients will also undergo an MRI scan of their lumbar spine. We will

then follow up with patients over 1 year with monthly pain diaries and the outcomes will be measured at 3 (short-term) and 12 months (long-term).

Intervention Type
Other

Primary outcome(s)
Pain persistence measured using the below at 3 months and 12 months:
1. The Sciatica Bothersomeness Index20 (SBI)
2. A Numerical Rating Scale (NRS)

Key secondary outcome(s))
1. Level of disability in activities of daily living measured using the Oswestry Disability Index at 3 and 12 months
2. Self-perceived change measured using a Global rating of change (GROC) scale at 3 and 12 months

3. Primary prognostic variables (collected at baseline):
3.1. Self-reported sensory profiling measured using the Neuropathic Pain Symptom Inventory (NPSI) and painDETECT questionnaires, and a body chart
3.2. Somatosensory profiling determined with the validated quantitative sensory testing protocol from the German Network for Neuropathic pain, and Conditioned Pain Modulation (CPM)
3.3. Psychosocial profile established through the Patient-Reported Outcomes Measurement Information System (PROMIS for anxiety, depression, fatigue, sleep disturbance, instrumental support, emotional support, ability to participate in social roles and activities), Adverse Childhood Events (ACEs), prolonged hospitalisation for a life-threatening condition (single question with yes/no answer), Pain Catastrophizing Scale (PCS), Ten-Item Personality Index (TIPI), State Optimism Measure (SOM-7), Sciatica Perception Questionnaire (SPQ), Stigma Scale for Chronic Illnesses (SSCI), and International Physical Activity Questionnaires (IPAQ)
3.4. Blood inflammatory markers measured using protein and metabolomic analyses

Additional phenotypic data assessed at baseline:
1. Demographic and medical information
2. Clinical examination
3. Self-reported questionnaires:
3.1. Prognostic indicators measured using the STarT Back Screening Tool
3.2. Health-related quality of life measured using the EuroQol EQ-5D questionnaire
3.3. Pain severity measured using a diary
3.4. Micro and macrostructural changes of lumbar nerve roots measured using magnetic resonance neurography in a subset of ~100 patients and ~50 healthy controls

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. People aged >18 years with a clinical diagnosis of ‘sciatica’
2. Sciatica symptom onset of the current episode within the past 3 months with a symptom-free period of at least 3 months preceding the current sciatica symptoms

3. A sum score of >4 (on the diagnostic model published by Stynes 2018) will be defined as sciatica (weighted sum score including self-reported sensory changes, below knee pain, leg pain worse than back pain, neurodynamic tests, and neurological deficit)
4. Clinical examination confirms the clinical diagnosis of sciatica and rules out other diagnoses

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
229

Key exclusion criteria
1. Presence of other nerve-related disorders (e.g. diabetic neuropathy, stroke)
2. Previous lumbar spine surgery
3. Serious spinal pathologies (e.g. infection, cauda equina syndrome, metastatic lesions)
4. Chronic inflammatory disorders
5. Other pain conditions that may confound assessment (e.g., fibromyalgia)
6. Pregnancy
7. Insufficient command of the English language to obtain consent/complete questionnaires
8. Contraindications to MRI for those selected for scanning

Date of first enrolment
15/05/2022

Date of final enrolment
23/09/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Oxford University
Nuffield Department of Clincial Neurosciences

John Radcliffe Hospital
West Wing Level 6
Oxford
United Kingdom
OX39DU

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Versus Arthritis

Alternative Name(s)
Arthritis UK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
National Institute for Health and Care Research

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
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository (Alleviate/ https://alleviate.ac.uk)

• The type of data that will be shared: All data presented in the final manuscript and outlined in the protocol.
• Dates of availability: expected to be available after publication of the main papers.
• Whether consent from participants was required and obtained: yes
• Comments on data anonymization: data will be anonymised
• Any ethical or legal restrictions: Data sharing agreements with Alleviate data hub are already in place.
• Any additional comments? For more information on Alleviate hub, see https://alleviate.ac.uk

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		05/04/2023	06/04/2023	Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes