

Improving the diagnosis and referral of patients with axial spondyloarthritis into specialist care

Submission date 28/11/2024	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 21/01/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/02/2025	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Axial spondyloarthritis (axSpA) is an inflammatory condition affecting 270,000 people in the UK, causing pain, stiffness and damage to the spine, pelvis and joint. Symptoms, including back pain, start in early adulthood and progress with time. Currently, it takes 5-8 years to get a diagnosis. Back pain is a common symptom and the minority have axSpA, so it is difficult for GPs to tell if back pain is due to inflammation. Effective treatments are available but delayed diagnosis leads to less benefit and worse health problems. To help General Practice Clinicians (GPCs) identify patients with inflammatory back pain faster to enable early diagnosis and timely access to treatment, we will design a new tool, to be integrated into GP computer systems, to help the GPCs decide if a patient needs to be referred to a specialist, and the impact of this on patients' wellbeing and delays in diagnosis.

Who can participate?

Adults aged 16-50 years who visit their GP for longstanding back pain (more than 3 months).

What does the study involve?

Participants will attend a research clinic, where they'll complete questionnaires and have a clinical examination, blood tests, x-rays and Magnetic Resonance Imaging (MRI) scans.

What are the possible benefits and risks of participating?

Taking part in the study may not directly benefit the patient but the information we collect from this study may help us to treat people with axSpA, and understand more about axSpA in the future. However, taking part in this study will include having an assessment in hospital with a rheumatology specialist, an x-ray (if aged 18 years or over) and an MRI scan. Once all the results have been reviewed by a specialist doctor, the patient and their GP will receive a letter with the results along with advice leaflets. The letter will state whether the patient is likely to have axSpA, or whether their back pain is likely to be non-inflammatory and due to other causes. This would be of benefit to some participants, with those receiving an axSpA diagnosis being offered rheumatology clinical follow-up.

The participant may experience discomfort from the blood test, however, this will not be any greater than would be experienced during a standard blood test for other purposes. As part of the study, the participant will be asked to have an MRI scan and an x-ray (if 18 years or older),

which are. MRI and x-rays are widely used in medical practice.

The study excludes patients who would have higher risks from MRI scans (pregnancy, retained ferrous metals, claustrophobia). We are all at risk of developing cancer during our lifetime. 50% of the population is likely to develop one of the many forms of cancer at some stage during our lifetime. The x-ray exposure from taking part in this study would comprise only an additional 0.001% chance of this happening.

Where is the study run from?

Nottingham Clinical Trials Unit at the University of Nottingham (UK)

When is the study starting and how long is it expected to run for?

January 2024 to September 2026

Who is funding the study?

The National Institute for Health and Care Research (NIHR); Programme Grant for Applied Research (PGfAR) reference NIHR205015 (UK)

Who is the main contact?

IDEAL Trial Management Team, ideal@nottingham.ac.uk

Study website

<https://ideal-backpacs.ac.uk/>

Contact information

Type(s)

Contact name

Dr IDEAL Trial Management Team

Contact details

Nottingham Clinical Trials Unit
Applied Health Research Building
School of Medicine
University of Nottingham
University Park
Nottingham
United Kingdom
NG7 2RD

-

ideal@nottingham.ac.uk

Type(s)

Scientific

Contact name

Prof Jon Packham

ORCID ID

<http://orcid.org/0000-0001-5531-1680>

Contact details

Rheumatology Department
Haywood Hospital
Midlands Partnership NHS Foundation Trust
Stoke-on-Trent
United Kingdom
ST6 7AG

-
jon.packham@mpft.nhs.uk

Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number

339400

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 64173, NIHR205015

Study information**Scientific Title**

Improving the Diagnosis and Early referral of patients with Axial spondyloarthritis- BACK Pain referral pathway from Community to Specialist care (IDEAL-BACKPACS)

Acronym

IDEAL - BACKPACS

Study objectives

The current 8-year diagnostic delay of axSpA can be reduced by validating/developing a specific axSpA referral strategy between primary care and specialist rheumatology in a UK healthcare setting.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 14/10/2024, Yorkshire & The Humber - Sheffield Research Ethics Committee (Meeting held by video-conference via Zoom; +44 (0)2071048139, +44 (0)2071048135, +44 (0)207 104 8210; sheffield.rec@hra.nhs.uk), ref: 24/YH/0188

Study design

Diagnostic test accuracy study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Participant information sheet available online at <https://ideal-backpacs.ac.uk/>

Health condition(s) or problem(s) studied

Axial spondyloarthritis

Interventions

Patients (aged 16-50 years) will be identified at their GP site (which will act as a Participant Identification Centre (PIC)) when consulting with chronic back pain. When the general practice clinician (GPC) enters a backpain code into the medical notes a brief study pop-up will alert the GPC that the patient may be suitable for the IDEAL-BACKPACS study. The GPC will be required to perform a basic eligibility screen to check the patient is eligible for the study and has no suspected red flags (i.e. anything to indicate the pain could be related to cancer, bone/disc infection, spinal fracture or Cauda Equina Syndrome). If appropriate, the GPC will ask the patient if they wish to hear more about the study. If they agree to hear more, the GPC will indicate on the pop-up that the patient is eligible, no suspected red flags and they are happy to receive more information. If these criteria are all met, an SMS text message will be sent to the patient with a link to the participant information sheet (PIS) and a link to indicate whether they are happy to speak with a member of the research team from their local participating hospital. The patient will provide contact details and a member of the research team will contact the patient.

The research team will go through the PIS with the patient, answer any questions and confirm eligibility. If the patient is eligible and happy to consent they will be provided with a link to the electronic Informed Consent form. A copy of the signed consent form will be sent to the participant from the study database. The research team will arrange a suitable time for the participant to attend a research clinic at their local secondary care site.

The patient will be asked to complete an electronic online questionnaire before their hospital visit.

During the hospital visit, the patient will have a clinical examination, provide relevant medical history, and have blood tests and an x-ray of their lower back and pelvis. The x-ray will be for participants aged 18 years and over. The patient will also have an MRI of their back and their pelvis. The MRI scan is likely to be on a separate visit, but could potentially be on the same day.

The participant will be informed whether or not they are likely to have axial spondyloarthritis (axSpA) or whether their back pain is likely to be due to non-inflammatory causes. All results will be forwarded to the participant's GP. The participant will also receive publicly available advice leaflets/website links, related to their diagnosis.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Sensitivity, specificity, likelihood ratio, calibration and discrimination of the Baraliakos strategy at baseline
2. Sensitivity, specificity, likelihood ratio, calibration and discrimination of the revised referral strategy at baseline

Secondary outcome measures

1. Sensitivity, specificity, likelihood ratio, calibration and discrimination of the Baraliakos strategy at baseline
2. Sensitivity, specificity, likelihood ratio, calibration and discrimination of the revised referral strategy at baseline
3. Sensitivity, specificity, likelihood ratio, calibration and discrimination of each strategy at baseline
4. Clinical effectiveness to be assessed via predictive performance measures (sensitivity, specificity, likelihood ratio, calibration and discrimination) comparing each strategy at baseline. Acceptability to be ascertained through discussion with stakeholders
5. Sensitivity, specificity, likelihood ratio, calibration and discrimination of NASS questionnaire at baseline
6. Diagnosis of AxSpa in a younger back pain cohort at baseline
7. Sensitivity, specificity, likelihood ratio, calibration and discrimination of individual screening variables at baseline

Overall study start date

01/01/2024

Completion date

30/09/2026

Eligibility**Key inclusion criteria**

1. Aged 16-50 years with the onset of chronic back (cervical/thoracic/lumbar) pain before 45 years
2. Current back pain and at least 3 consecutive months of chronic back pain in the last 12 months
3. Ability to provide written/electronic informed consent
4. Willingness and ability to undergo study assessments (i.e., clinical assessment, X-ray, MRI, blood sample collection)

Participant type(s)

Patient

Age group

Adult

Lower age limit

16 Years

Upper age limit

50 Years

Sex

Both

Target number of participants

Planned Sample Size: 900; UK Sample Size: 900

Key exclusion criteria

1. Existing diagnosis of axSpA
2. Existing diagnosis of inflammatory arthritis
3. GPC deems unsuitable
4. Radiation of leg pain below the knee (i.e. neuralgia/sciatica)
5. Contraindications to MRI, eg:
 - 5.1. Pacemaker
 - 5.2. Other ferrous metal in situ
 - 5.3. Pregnancy (up to 12 months postpartum)
 - 5.4. Claustrophobia
6. Suspected red flags in the history or clinical examination that may indicate further investigation or referral for possible serious underlying pathology:
 - 6.1. Cauda Equina Syndrome
 - 6.2. Spinal Fracture
 - 6.3. Cancer
 - 6.4. Bone/disc infection

Date of first enrolment

03/03/2025

Date of final enrolment

31/03/2026

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Midlands Partnership University NHS Foundation Trust

Trust Headquarters

St Georges Hospital

Corporation Street

Stafford
United Kingdom
ST16 3SR

Study participating centre

Royal United Hospitals Bath NHS Foundation Trust
Combe Park
Bath
United Kingdom
BA1 3NG

Study participating centre

Liverpool University Hospitals NHS Foundation Trust
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre

Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre

Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

Sponsor information

Organisation

University of Nottingham

Sponsor details

E-Floor
Yang Fujia Building
Jubilee Campus
Wollaton Road
Nottingham
England
United Kingdom
NG8 1BB
+44 (0)7866 137607
sponsor@nottingham.ac.uk

Sponsor type

University/education

Website

<http://www.nottingham.ac.uk/>

ROR

<https://ror.org/01ee9ar58>

Funder(s)**Funder type**

Government

Funder Name

NIHR Central Commissioning Facility (CCF)

Results and Publications**Publication and dissemination plan**

1. Planned publications in a high-impact peer-reviewed journal – publication by March 2027
2. Research impact accelerator unit involvement from Keele University
3. Presentations at international conferences
4. Incorporation into national axSpA clinical guidelines

Intention to publish date

01/03/2027

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from the Nottingham Clinical Trials Unit. Anonymised, participant-level data will be available following the publication of results by the study team at the end of the programme grant.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.1	09/10/2024	18/12/2024	No	No