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

Submission date
28/11/2024

Recruitment status
Recruiting

Registration date
21/01/2025

Overall study status
Ongoing

Last Edited
05/01/2026

Condition category
Musculoskeletal Diseases

[X] 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
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

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
339400

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
AxiaL spondyloarthritis

Interventions
Current interventions as of 31/12/2025:
Patients (aged 16-50 years with chronic back pain of ≥3 consecutive months' duration and onset before 45 years) will be identified at their GP site (which will act as a Participant Identification Centre (PIC)) through monthly retrospective electronic health record searches. Using pre-specified SNOMED codes, GP practices will search their clinical record system to identify patients who have recently consulted with back pain.

Following the search, the general practice clinician (GPC) will perform a basic screen of the potentially eligible patients identified to remove any patients who are inappropriate to invite onto the study). A full study eligibility check will be performed by the secondary care site research team. If appropriate, 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 securely via the study database 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 (eISF). 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.

Previous 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.

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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

Primary outcome(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Upper age limit
50 years

Sex
All

Total final enrolment
0

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
30/06/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Midlands Partnership University NHS Foundation Trust
Trust Headquarters
St Georges Hospital
Corporation Street
Stafford
England
ST16 3SR

Study participating centre
Royal United Hospitals Bath NHS Foundation Trust
Combe Park
Bath
England
BA1 3NG

Study participating centre
Liverpool University Hospitals NHS Foundation Trust
Royal Liverpool University Hospital
Prescot Street
Liverpool
England
L7 8XP

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street

Leeds
England
LS9 7TF

Study participating centre
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Colney
Norwich
England
NR4 7UY

Sponsor information

Organisation
University of Nottingham

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

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?
Participant information sheet		11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.1	09/10/2024	18/12/2024	No	No
Protocol file	version 1.2	30/07/2025	09/09/2025	No	No
Study website		11/11/2025	11/11/2025	No	Yes