ISRCTN30265575 https://doi.org/10.1186/ISRCTN30265575

A study to investigate how common a diagnosis of axial spondyloarthritis (axSpA) is in patients with known inflammatory bowel disease (IBD) such as Crohn's Disease and Ulcerative Colitis, and the development of a tool to direct referral of patients with suspected axSpA in IBD patients to a rheumatology specialist.

Submission date
04/04/2018

Recruitment status
No longer recruiting

Registration date
20/04/2018

Overall study status
Completed

Last Edited
30/08/2022

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Inflammatory bowel disease (IBD) describes long-term conditions that involve inflammation (swelling) of the gut. This can sometimes be associated with an arthritis called Axial Spondyloarthritis (axSpA). The arthritis causes inflammation in the spine resulting in back pain, stiffness or reduced range of movement of the spine. AxSpA is often diagnosed late because it is a relatively uncommon cause of back pain and there are many other cause of back pain which may be investigated by the doctor first. It is, however, important to make this diagnosis as early as possible in order to receive the most effective treatment.
This study aims to find out how many people with IBD also have axSpA. Further study of these participants' characteristics will help us to develop a tool to guide investigations in patients with IBD. This aims to reduce the time to diagnosis and enable the earlier access to available treatments.

Who can participate?
Adults aged between 18 and 80 with inflammatory bowel disease

What does the study involve?
Patients with a known diagnosis of inflammatory bowel disease attending hospital appointments for this are invited to participate in the study via a postal questionnaire. If patients are deemed eligible, participants are invited to attend an assessment in the Rheumatology Department consisting of a medical interview, physical examination, blood tests and an X-ray, and a second appointment for an MRI scan of the back and pelvis.

What are the possible benefits and risks of participating?
Participants may benefit from finding an explanation for their back pain. If they are found to have inflammation in their spine or other potentially treatable causes of back pain, we recommend that their GP refer them to the main rheumatology clinic and they may be given some different treatment to help manage their symptoms.
The new diagnosis of axSpA may have implications for the participants day-to-day life (as being diagnosed with any chronic disease would) but this will allow an opportunity to start treatment earlier which is likely to outweigh any distress caused.

Where is the study run from?
Norfolk and Norwich University Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2017 to July 2019

Who is funding the study?
National Ankylosing Spondylitis Society (NASS) (UK)

Who is the main contact?
Dr Chong Seng Edwin Lim
edwin.lim@nnuh.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Dr Edwin Lim

ORCID ID
http://orcid.org/0000-0003-2355-7410

Contact details
Rheumatology Department
Norfolk & Norwich University Hospital
Colney Lane
Norwich
United Kingdom
NR4 7UY

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

223356 (118-07-17)

Study information

Scientific Title
Axial Spondyloarthritis in Inflammatory Bowel Disease – secondary care cross-sectional prevalence and development of an evidence-base referral tool [Norfolk - Axial SPa Ibd REferral Tool (N-ASPIRE Tool)]

Acronym
N-ASPIRE Tool

Study objectives
This study investigates how common a diagnosis of axial spondyloarthritis (axSpA) is in patients with known inflammatory bowel disease (IBD) such as Crohn's Disease and Ulcerative Colitis. We hope to use information from the study to develop a tool to direct referral of patients with suspected axSpA in IBD patients to a rheumatology specialist.

IBD causes inflammation of the gut leading to symptoms such as diarrhoea, abdominal pain, back passage bleeding. AxSpA is a condition that causes inflammation in the spine resulting in back pain, stiffness, reduced range of spinal movement and fatigue. Recent research has shown that there are close associations between the two conditions. Because of advances in Magnetic Resonance Imaging (MRI), it is now possible to diagnose axSpA before changes become apparent on radiography (X-ray). However, this condition is still being diagnosed late because back pain is common and axSpA is a relatively uncommon cause of back pain. Identification strategies typically focus on patients in primary care, however there is an undefined population of undiagnosed patients with axSpA-associated conditions being seen in secondary care.

We feel that it is important to understanding how common axSpA is in IBD patients as the undiagnosed cases may represent a "hidden burden" of axSpA. This will then allow further analysis to facilitate the development of a referral tool to improve identification, thereby reducing the diagnostic delay and enable access to effective treatments.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridgeshire and Hertfordshire Research Ethics Committee (Research Ethics Committee), 25 /05/2018, ref: 18/EE/0102

Study design
Observational cross-sectional cohort study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)

Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Axial Spondyloarthritis / Ankylosing Spondylitis

Interventions
Patients with a known diagnosis of IBD attending gastroenterology appointments are invited to participate in the study via a postal questionnaire. If patients are deemed eligible, participants are invited to attend an assessment in the Rheumatology Department consisting of a medical interview, physical examination, blood tests and an X-ray, and another appointment for an MRI scan of the back and pelvis.
The N-ASPIRE referral tool is an algorithm that is developed at the analysis stage of the study formulated using data gathered from the trial.

Intervention Type
Other

Primary outcome measure
1. Total number of participants given a physician verified diagnosis of axial spondyloarthritis is recorded at the assessment.
2. Number of participants given a new physician verified diagnosis of axial spondyloarthritis is recorded at the assessment.
3. The sensitivity and specificity of the N-ASPIRE referral tool is assessed using positive and negative predictive values including likelihood ratios and diagnostics odd ratio.

Secondary outcome measures
N/A

Overall study start date
24/01/2017

Completion date
25/07/2019

Eligibility

Key inclusion criteria
Inclusion criteria for Phase 1 (Screening):
1. Gastroenterologist verified diagnosis of inflammatory bowel disease (Crohn’s disease or Ulcerative colitis, with either endoscopic, radiological or histological evidence of disease based on established criteria)

2. Age ≥ 18 and ≤ 80 years old
3. Patient willing and able to participate in the study
4. Including known/previous diagnosis of AS or axSpA

Inclusion criteria for Phase 2 (Clinical assessment):
1. Chronic back pain (≥ 3 months)
2. Onset of back pain before 45 years old
3. Including known/previous diagnosis of AS or axSpA (if unable to verify diagnosis retrospectively)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
390

Total final enrolment
470

Key exclusion criteria
1. Any type of biologic therapy for (previous or current) treatment of IBD
2. Unable to tolerate MRI scanning (e.g. current history of claustrophobia) or contra-indication to MRI scanning
(including but not limited to e.g. pacemaker, pregnancy, metallic or conducting foreign body, etc.)
3. Age <18 or >80 years
4. Patients lacking in capacity and/or unable to give informed consent
5. Patients unable to understand English to sufficient degree to be able to complete a questionnaire
6. Illiteracy
7. Prisoners
8. Patient unwilling to take part in the study

Date of first enrolment
01/05/2018

Date of final enrolment
25/12/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
NORFOLK AND NORWICH UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
Colney Lane
Norwich
United Kingdom
NR4 7UY

Sponsor information

Organisation
Norfolk and Norwich University Hospitals NHS Foundation Trust

Sponsor details
R&D Office, Level 3 East Block
Norfolk & Norwich University Hospitals NHS Foundation Trust
Colney Lane
Norwich
England
United Kingdom
NR4 7UY

Sponsor type
Hospital/treatment centre

Website
http://www.nnuh.nhs.uk/research-and-innovation/

ROR
https://ror.org/01wspv808

Organisation
University of East Anglia (UEA) – Co-sponsor

Sponsor details
Research and Innovation Services (RIN) Registry
University of East Anglia
Norwich Research Park
Norwich
England

United Kingdom
NR4 7TJ

Sponsor type
University/education

Funder(s)

Funder type
Charity

Funder Name
National Ankylosing Spondylitis Society (NASS)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal estimated 2020.

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Edwin Lim. edwin.lim@nnuh.nhs.uk.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		22/08/2022	30/08/2022	Yes	No
HRA research summary			26/07/2023	No	No