

# How common is lower back inflammation in patients with known inflammatory bowel disease such as Crohn's disease and ulcerative colitis picked up on imaging for their bowel symptoms?

<b>Submission date</b> 25/02/2019	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/02/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/10/2023	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Background and study aims.

Inflammatory bowel disease can sometimes be associated with a form of arthritis known as axial spondyloarthritis. This arthritis causes inflammation of the spine resulting in back pain, stiffness and reduced range of movement. AxSpA is often diagnosed late because it is a relatively uncommon cause of back pain and there are many other causes of back pain which may be considered by your doctor first. It is, however, important to make this diagnosis as early as possible in order to receive the most effective treatment. This study is designed to find out how many people with IBD [who have previously had an abnormal CT scan] also have axSpA. This knowledge will increase awareness of axSpA in IBD, and may suggest an alternative identification route for such patients. This aims to reduce the time to diagnosis and enable earlier access to available treatments.

## Who can participate?

Adult patients with pre-existing IBD (CD or UC), with a previous CT scan highly suggestive of axSpA, as identified by the radiology team at the Norfolk and Norwich University Hospital (NNUH).

## What does the study involve?

Patients with a known diagnosis of IBD who had a previous CT scan for their bowel disease and in whom there are imaging features highly suggestive of axSpA. These patients will have been identified via a service evaluation review undertaken by the radiology department. Patients will be invited to participate in the study via a postal questionnaire. If patients are deemed eligible, they will be invited to attend an assessment in the Rheumatology Department consisting of a medical interview, physical examination, blood tests, and an MRI scan of the spine and pelvis.

What are the possible risks and benefits of participating?

Participants will have an opportunity to find 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 will recommend that their GP refer them to the main rheumatology clinic and they may be given some different treatment to help manage their symptoms.

What are the possible risks of participating?

The new diagnosis of axSpA may have implications for the participants' day-to-day life (as being diagnosed with any chronic disease would), however as this will offer an opportunity to start treatment, this is likely to outweigh any distress caused.

There are some risks and discomfort associated with the study procedures outlined below:

- Blood collection: For most people, needle punctures for blood withdrawal do not cause any problems. However, sometimes they may cause bleeding, bruising, discomfort, infections, and /or pain where the skin is punctured. They may also feel dizzy.

- MRI: The risks associated with having an MRI of the spine and pelvis are very minimal.

Participants who are claustrophobic (have a fear of closed spaces) or have had any metal placed in your body (for example, during surgery) may not be able to have the investigation.

As with any test, there is always a possibility that the results of the above investigations may identify another cause for one's symptoms that may be unrelated to the study. This information will be forwarded to the participant and their general practitioner who will decide on their further care.

Where is the study run from?

Norfolk and Norwich University Hospital (NNUH) in the United Kingdom

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

July 2019 to June 2020

Who is funding the study?

Pharmaceutical company AbbVie (the company only provides the funding to support the research, but has no influence on the design, conduct, management of the study. The company will not have access to any personal identifiable data)

Who is the main contact?

Dr Edwin Lim

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## Contact information

**Type(s)**

Public

**Contact name**

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### **Type(s)**

Scientific

### **Contact name**

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## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **ClinicalTrials.gov (NCT)**

Nil known

### **Protocol serial number**

252117 (133-10-18)

## **Study information**

### **Scientific Title**

What proportion of patients with Inflammatory Bowel Disease have Axial Spondyloarthritis – An imaging referral strategy utilising Computed Tomography defined Sacroiliitis [Norfolk - Axial SPa Ibd REferral Computed Tomography Strategy (N-ASPIRE CT Strategy)]

### **Acronym**

N-ASPIRE CT Strategy

### **Study objectives**

How common is the diagnosis of axial spondyloarthritis (axSpA) in patients with known inflammatory bowel disease (IBD) such as Crohn's Disease and Ulcerative Colitis who have previously had an abnormal Computed Tomography (CT) scan?

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 20/05/2019, East of England - Essex Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; Email: nrescommittee.eastofengland-essex@nhs.net), ref: 19/EE/0125

Assessed 15/02/2019, London Bridge Research Ethics Committee REC (Henriette Raphael House, Boardroom, Ground Floor, Henriette Raphael House, Guy's Campus, King's College London, SE1 1UL, Tel: +44 (0)207 104 8222, Email: NRESCCommittee.London-LondonBridge@nhs.net), ref: 19/LO/0424. This review was subsequently transferred to East of England - Essex Research Ethics Committee.

### **Study design**

Observational cross-sectional cohort study

### **Primary study design**

Observational

### **Study type(s)**

Screening

### **Health condition(s) or problem(s) studied**

Axial Spondyloarthritis / Ankylosing Spondylitis, Spondyloarthritis, Rheumatology

### **Interventions**

This is being undertaken as part of good clinical practice. Patients with a diagnosis of IBD who underwent a CT scan, and in whom there are suspicious features of axSpA will be invited to participate in the study via a postal questionnaire. If patients are considered eligible, participants will then be invited to attend an assessment in the Rheumatology Department. This will comprise an expert medical interview, physical examination, blood tests and an MRI scan of the spine and pelvis.

### **Intervention Type**

Other

### **Primary outcome(s)**

Proportion of Inflammatory Bowel Disease patients with incidental Computed Tomographic defined Sacroiliitis (CTSI) who have a rheumatologist-verified diagnosis of Axial Spondyloarthritis

### **Key secondary outcome(s)**

1. Proportion of patients who fulfil the Assessment of Spondyloarthritis International Society (ASAS) classification criteria for Axial Spondyloarthritis
2. Proportion of symptomatic vs asymptomatic incidental CTSI

**Completion date**

14/06/2020

## Eligibility

**Key inclusion criteria**

Inclusion criteria for Phase 1 (postal survey):

1. CT scan performed for non-musculoskeletal indications
2. Age between 18 and 55 years old inclusive at the time of CT scan
3. Verified IBD diagnosis (by gastroenterologist via gastroenterology clinical letter +/- supportive histology/radiology results using electronic medical, lab, radiology records)
4. Presence of incidental Computer Tomographic defined Sacroiliitis (CTSI) which is defined as the presence of sacroiliac joint ankylosis or total erosion score (TES) of  $\geq 3$  or  $> 0.5$  cm iliac sclerosis or  $> 0.3$  cm sacral sclerosis

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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

27

**Key exclusion criteria**

1. 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.)
2. Age  $< 18$  or  $> 55$  years
3. Lacking in capacity and/or unable to give informed consent
4. Unable to understand English to sufficient degree to be able to complete a questionnaire
5. Illiteracy
6. Prisoners
7. Unwilling to take part in the study

**Date of first enrolment**

01/08/2019

**Date of final enrolment**

31/10/2019

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**NORFOLK AND NORWICH UNIVERSITY HOSPITALS NHS FOUNDATION TRUST**

Norfolk & Norwich University Hospital

Colney Lane

Norwich

United Kingdom

NR4 7UY

## Sponsor information

**Organisation**

Norfolk & Norwich University Hospital NHS Foundation Trust (NNUH) - Lead Sponsor

**Organisation**

University of East Anglia (UEA) – Co-sponsor

## Funder(s)

**Funder type**

Industry

**Funder Name**

AbbVie

**Alternative Name(s)**

AbbVie Inc., AbbVie U.S., AbbVie US, Allergan

## Funding Body Type

Government organisation

## Funding Body Subtype

For-profit companies (industry)

## Location

United States of America

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		15/10/2022	25/10/2023	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No