ISRCTN11108086 https://doi.org/10.1186/ISRCTN11108086

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?

Submission date
25/02/2019

Recruitment status
No longer recruiting

Registration date
26/02/2019

Overall study status
Completed

Last Edited
25/10/2023

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 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?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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) is 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: NRESCommittee.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

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

Secondary outcome measures
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

Overall study start date
01/01/2017

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 ≥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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
27

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
England

United Kingdom

Study participating centre
NORFOLK AND NORWICH UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
Norfolk & Norwich University Hospital
Colney Lane
Norwich
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NR4 7UY

Sponsor information

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

Sponsor details
Sponsor Contact - Julie Dawson
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Sponsor type
Hospital/treatment centre

Website
http://www.nnuh.nhs.uk/

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

Sponsor details
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Sponsor type
University/education

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal estimated 2021.

Intention to publish date
31/12/2022

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?
HRA research summary			28/06/2023	No	No
Results article		15/10/2022	25/10/2023	Yes	No