

Prevalence of SpondyloArthropathies in Norfolk

Submission date 20/07/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 07/11/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/01/2016	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
The prevalence of inflammatory back pain and SpondyloArthropathies in a primary care population in Norfolk

Acronym

Study objectives

Axial SpA (AS) is an inflammatory condition affecting the spine, peripheral joints and extra-articular systems. Untreated it can lead to ankylosis of the sacro-iliac joints and spine. Anti-TNF drugs can improve symptoms, but drug-free remission can usually be achieved only in patients with early disease who have not yet developed radiographic changes. There is therefore a pressing need to identify patients early in the course of disease. One way to do this is to find those with inflammatory back pain (IBP), the earliest and commonest symptom of SpA.

Estimates of the prevalence of IBP in the UK are based on a single study, published in 1995 [Underwood and Dawes. Br J Rheumatol 1995; 34:1074-7]. In this study, 313 patients with chronic back pain were screened for inflammatory back pain using a GP-administered questionnaire. 15% scored positively and were subsequently examined. Two patients were found to have AS, and 18 had features of an inflammatory arthropathy. The authors concluded that up to 5% of patients with chronic back pain might have a mild form of AS.

We have developed and validated a patient-administered questionnaire and want to use this in a primary care population with low back pain to identify those with possible inflammation. Advances in imaging techniques, and the more widespread availability of magnetic resonance imaging (MRI) scanning in the past 15 years, should allow us to identify with more certainty which of those patients with IBP actually have an inflammatory spondyloarthropathy.

This will enable us to determine the prevalence of inflammatory back pain and SpA in primary care, and evaluate the diagnostic utility of various clinical parameters.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee East of England, Norfolk, 05/08/2011, ref: 11/EE/0245

Study design

Single-centre cross-sectional cohort study

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Axial spondyloarthropathy, ankylosing spondylitis

Interventions

Participants will be asked to complete a screening questionnaire for inflammatory back pain. A subgroup (comprising 75 positive-scoring cases and 25 age and sex-matched negative-scoring controls) will then be assessed more fully with history and examination, a blood test for HLA-B*27 and erythrocyte sedimentation rate (ESR), and outcome measure questionnaires [Bath

Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Ankylosing Spondylitis Quality of Life (ASQoL)]. This group will also be invited to have an MRI scan of the sacroiliac joints and whole spine. Follow-up will end after the MRI scan.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Inflammatory back pain questionnaire score

Key secondary outcome(s)

1. MASES
2. HLA-B*27 status
3. BASDAI
4. BASFI
5. BASMI
6. ASQoL
7. AS-DAS
8. MRI scan result

Completion date

01/07/2012

Eligibility**Key inclusion criteria**

1. Male or female aged 18 and over
2. Have ever attended GP with back pain
3. Willing and able to give informed consent to take part in study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Unwilling to take part in study
2. Identified as unsuitable for inclusion by GP
3. Unable to communicate in English (as screening questionnaire not validated in translation)
4. Patients will be excluded from the MRI scanning phase of the study if this is contra-indicated (e.g. cardiac pacemaker)

Date of first enrolment

01/09/2011

Date of final enrolment

01/07/2012

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Norfolk and Norwich University Hospital

Norwich

United Kingdom

NR4 7UY

Sponsor information

Organisation

University of East Anglia (UK)

ROR

<https://ror.org/026k5mg93>

Funder(s)

Funder type

Industry

Funder Name

Pfizer (UK)

Alternative Name(s)

Pfizer Inc., Pfizer Consumer Healthcare, Davis, Charles Pfizer & Company, Warner-Lambert, King Pharmaceuticals, Wyeth Pharmaceuticals, Seagen, Pfizer Inc

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**IPD sharing plan summary****Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2014		Yes	No
Results article	results	21/12/2015		Yes	No