

# Prevalence of SpondyloArthropathies in Norfolk

<b>Submission date</b> 20/07/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 07/11/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 14/01/2016	<b>Condition category</b> 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

### Contact name

Dr Louise Hamilton

### Contact details

Rheumatology Department  
Norfolk and Norwich University Hospital  
Colney Lane  
Norwich  
United Kingdom  
NR4 7UY

-

[louise.hamilton@nnuh.nhs.uk](mailto:louise.hamilton@nnuh.nhs.uk)

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

**Scientific Title**

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

**Acronym**

PSpAN

**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

**Secondary study design**

Cross sectional study

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

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

Axial spondyloarthritis, 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 measure**

Inflammatory back pain questionnaire score

**Secondary outcome measures**

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

**Overall study start date**

01/09/2011

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

1000

**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**

England

United Kingdom

**Study participating centre**

**Norfolk and Norwich University Hospital**

Norwich

United Kingdom

NR4 7UY

## **Sponsor information**

**Organisation**

University of East Anglia (UK)

**Sponsor details**

Norwich Research Park  
Norwich  
England  
United Kingdom  
NR4 7TJ

**Sponsor type**

University/education

**Website**

<http://www.uea.ac.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

**Funding Body Type**

Government organisation

**Funding Body Subtype**

For-profit companies (industry)

**Location**

United States of America

**Results and Publications****Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan**

## IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/01/2014		Yes	No
<a href="#">Results article</a>	results	21/12/2015		Yes	No