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Prevalence of SpondyloArthropathies in Norfolk

Submission date	Recruitment status	[ ] Prospectively registered
20/07/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/11/2011	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/01/2016	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 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 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
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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?
Results article	results	01/01/2014		Yes	No
Results article	results	21/12/2015		Yes	No