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Diagnostic accuracy of recently proposed criteria for inflammatory back pain (IBP) in suspected ankylosing spondylitis (AS) and early axial spondyloarthritis (axial SpA)

Submission date	Recruitment status	[X] Prospectively registered
11/07/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/08/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/08/2008	Musculoskeletal Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Martin Rudwaleit

Contact details
Hindenburgdamm 30
Berlin
Germany
12200
+49 (0)30 8445 4547
martin.rudwaleit@charite.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Acronym
DIVERS

Study objectives
Sensitivity of at least 70% and specificity of at least 70% for the previously proposed criteria for inflammatory back pain (IBP).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ethics Committee of Charité - University Medicine Berlin on the 8th July 2008 (ref: EA4/058/08).

Study design
Observational diagnostic accuracy study

Primary study design
Observational

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
Ankylosing spondylitis (AS), early axial spondyloarthritis (axial SpA)

Interventions
Experimental group (no medical intervention):
The diagnostic accuracy of IBP will be investigated in four private practices and two hospitals by assessing IBP by an independent and blinded observer (rheumatologist in each setting) in patients with undiagnosed chronic back pain who are referred because of suspected SpA.

IBP will also be assessed by primary care physicians or orthopaedists in patients with chronic back pain of unclear origin, and also self-assessed by the patient prior to referral to the Rheumatology Department at Charité CBF for further work-up.

The total duration of the trial is two years. There is no follow-up.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Sensitivity, specificity and positive likelihood-ratio (LR+) if two out of four parameters of IBP are present.

Secondary outcome measures
Sensitivity, specificity and positive likelihood-ratio (LR+) if three or four out of four parameters of IBP are present.

Overall study start date
01/09/2008

Completion date
01/08/2010

Eligibility

Key inclusion criteria
Patients (aged greater tha 18 years, either sex) with chronic back pain (greater than 3 months) of unknown origin:
1. Referred to the rheumatologist because of suspected AS/axial SpA
2. Seen by primary care physicians/orthopaedists, who agree to subsequently be referred to the rheumatologists

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
550

Key exclusion criteria
Patients with a definite diagnosis (cause) related to their back pain.

Date of first enrolment
01/09/2008

Date of final enrolment
01/08/2010

Locations

Countries of recruitment
Germany

Study participating centre
Hindenburgdamm 30
Berlin
Germany
12200

Sponsor information

Organisation
Charite - University Medicine Berlin (Charite - Universitatsmedizin Berlin) (Germany)

Sponsor details
c/o Dr. Krukenkamp
Charitéplatz 1
Virchowweg 1
Berlin
Germany
10117
c.krukenkamp@charite.de

Sponsor type
University/education

Website
http://www.charite.de/

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
Research council

Funder Name
German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany)

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