

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

Submission date 11/07/2008	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 19/08/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/08/2008	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

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

Completion date

01/08/2010

Eligibility

Key inclusion criteria

Patients (aged greater than 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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 - Universitätsmedizin Berlin) (Germany)

ROR

<https://ror.org/001w7jn25>

Funder(s)

Funder type

Research council

Funder Name

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration