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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**
11/07/2008

**Recruitment status**
No longer recruiting

**Registration date**
19/08/2008

**Overall study status**
Completed

**Last Edited**
19/08/2008

**Condition category**
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

## 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).

## Primary study design
Observational

## Study design
Observational diagnostic accuracy study

## 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 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

### 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 - Universitatsmedizin 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