

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

<b>Submission date</b> 11/07/2008	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 19/08/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 19/08/2008	<b>Condition category</b> 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

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## 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 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

**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 - Universitätsmedizin Berlin) (Germany)

**Sponsor details**

c/o Dr. Krukenkamp

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**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