# 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

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# 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 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

# **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet 11/11/2025 No Yes