ASAS CLassification of Axial SpondyloarthritiS Inception Cohort in the Netherlands

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Primary study objectiveTo validate the performance of the current ASAS classification criteria in a prospective combined cohort of patients presenting to a rheumatologist in North America, Europe, and other parts of the world with undiagnosed...

Ethical review	Approved WMO
Status	Completed
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON48283

Source
ToetsingOnline

Brief title
ASAS CLASSIC study - the Netherlands

Condition

- Joint disorders

Synonym
ankylosing spondylitis, axial spondyloarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: ASAS stichting

Intervention

Keyword: Classification, Epidemiology, Spondyloarthritis

Outcome measures

Primary outcome

Primary Endpoint

ASAS classification criteria that attain specificity of >=90% and sensitivity of >=75%.

If the primary endpoint is met, the protocol will stop and no further analyses that aim to modify the criteria will be made.

Secondary outcome

Secondary Endpoints (For assessing the impact of educational intervention)

1. Agreement for detection of MRI lesions on a dichotomous basis (present/absent) between central and local investigators.

2. Agreement for detection of ASAS positive MRI between central and local investigators.

3. Frequency of diagnostic re-categorization by local investigator BEFORE and AFTER central image review and education.

4. Confidence of diagnostic ascertainment by the local investigator after assessment of all obtained information before the central image review and education over time.

5. Agreement between final diagnosis of the local rheumatologists, which is made after being informed about and after having discussed the imaging findings by the central readers, with the diagnosis made by the central clinical committee.

Tertiary Endpoint

Predictive validity of the ASAS classification criteria over a five-year

period, both for the pooled axSpA classification criteria for axSpA as for the

imaging and clinical arm separately.

Study description

Background summary

The Assessment of SpondyloArthritis international Society (ASAS) group has developed classification criteria for axial spondyloarthritis (axSpA) that allow the inclusion of patients with an early form of disease that is not yet clearly visible on plain radiography. These criteria include both an *imaging arm*, that incorporates either radiographic sacroiliitis or magnetic resonance imaging (MRI) features of inflammation in the sacroiliac joints (SIJ) plus one clinical feature of spondyloarthritis (SpA), and a *clinical arm* that requires the presence of human leukocyte antigen-B27 (HLA-B27) plus 2 clinical features of SpA. The sensitivity and specificity of these criteria for axSpA were 83% and 84%, respectively, in patients with undiagnosed chronic back pain and suspicion of SpA. The external standard for evaluation of these criteria was the rheumatologist expert opinion of the SpA diagnosis after incorporating lab and imaging data with clinical evaluation.

Since their introduction, some have raised concerns regarding the ASAS classification criteria as substantial differences in the prevalence estimates of axSpA have been found. One of these concerns are that the criteria may have been misused as a checklist of SpA features to diagnose patients rather than following a diagnostic process of clinical reasoning based on all available information by an experienced clinician rheumatologist who then formulates a final diagnostic opinion before the classification criteria are applied.

Despite all concerns, a five-year follow-up of the ASAS classification cohort has reported high positive predictive value of the axSpA criteria with no differences between the clinical and the imaging arm. However, more than half of the collected patient information was obtained by telephone interviews.

It has been suggested that further education regarding appropriate ascertainment of SpA features and evaluation of imaging might help to reduce misclassification and to prevent that the criteria are inappropriately used as a basis for diagnostic evaluation of SpA. With effective medication now available for several years, and effectiveness being particularly apparent in

early disease, reducing diagnostic delay is a priority.

A joint meeting of the ASAS and the SpA Research and Treatment Network (SPARTAN) executive boards has recommended that the ASAS classification criteria undergo further validation in a prospective cohort in North American (United States and Canada) and in a prospective cohort in Europe and other parts of the world of patients presenting with undiagnosed active chronic back pain to rheumatologists. Other differentiating features for this study, as compared to the original ASAS classification criteria study, will be 1) central image review and education on MRI and radiography for local investigators and 2) the comparison of the final diagnosis of the local rheumatologists with a central clinical committee diagnosis as applied for new classification criteria for systemic sclerosis and for SLE. This would serve to educate both rheumatologists and radiologists in evaluating imaging for the diagnosis of axSpA and to enhance confidence in the external standard determination of the diagnosis of axSpA.

Study objective

Primary study objective
To validate the performance of the current ASAS classification criteria in a prospective combined cohort of patients presenting to a rheumatologist in North America, Europe, and other parts of the world with undiagnosed current back pain of >=3 months duration with onset <=45 years of age. If a specificity of >=90% and a sensitivity of >=75% of the original ASAS criteria will be found in the study, the ASAS criteria will be considered validated and no further analyses will be done. Only if the primary objective is not met, refinements of the criteria will be made and tested.

Secondary study objectives
1. To compare the ascertainment of sacroiliitis by MRI and the confidence of this ascertainment by local investigators at sites across North America and worldwide before and after interactive educational intervention. The educational intervention with the local investigators will consist of formal reporting, extensive DICOM-image annotation, and live case discussion provided by the central readers. The central readers are musculoskeletal radiologists and rheumatologists with extensive expertise (>5 years* experience) in the assessment of axSpA.
2. To compare the final diagnosis of the local rheumatologists, which is made after being informed about and after having discussed the imaging findings by the central readers, with the diagnosis made by the central clinical committee.

Tertiary study objective
To determine the predictive validity of the ASAS classification criteria (also split by imaging and clinical arm) over a five-year period.

Study design

Observational, longitudinal (visit at baseline and 5 years), multi-centric, worldwide study. This protocol applies to centres in the Nederlands.

Study burden and risks

The burden can be considered to be very low. Information is obtained from patient records or the treating physician at baseline and 5-years follow-up. Patients receive usual care and they will not receive any intervention. Since the nature of this study is observational, and the burden on the participants is very low, there will not be any risks in taking part in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Consecutive patients with current undiagnosed low back and/or buttock pain with onset <=45 years and duration >=3 months referred to the rheumatology department for diagnosis in the Netherlands.

Exclusion criteria

- Patients with no back and/or buttock pain during last week
- Patients with back and/or buttock pain that lasted less than 3 months
- Patients with an onset of back and/or buttock pain after 45 years of age
- Patients with pain localized to the groin instead of back pain
- Patients with a prior rheumatologist confirmed diagnosis of SpA

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	11-01-2020
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	15-05-2019
Application type:	First submission

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL68287.058.19