Amsterdam Spondyloarthritis cohort (AmSpA cohort)

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

Summary

ID

NL-OMON47286

Source
ToetsingOnline

Brief title
AmSpA cohort

Condition

- Joint disorders

Synonym
Spondyloarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: overarching cohort, Spondyloarthritis

Outcome measures

Primary outcome

Parameters that were collected during the regular visits at the outpatient clinic are: (changes in) disease activity (BASDAI and ASDAS and inflammatory markers (CRP- and ESR-levels), frequency of adverse events and drug adherence and response during biological treatment and disease progression (radiographic changes on X-rays and /or MRI, and change of classification from nr-axial SpA to AS). In addition, parameters concerning changes in function (BASFI), in range of motion (BASMI), occurrence of extra-articular manifestations and comorbidities and BMD change (DEXA scans) were collected during the regular visits.

Secondary outcome

n.a.

Study description

Background summary

Background: In 1999 a prospective cohort study (Early SpA cohort) was initiated in Amsterdam (Reade) with inclusion of consecutive early SpA patients who either fulfilled the modified New York criteria of Ankylosing Spondylitis (AS) or the ESSG criteria of SpA and had a disease duration of less than two years, of which currently, 275 patients are included. From 2002 onwards several cohorts were established consisting of AS patients who were treated with a TNF inhibitor (TNFi), for each separate type of drug (infliximab (50 patients), etanercept (203 patients), adalimumab (165 patients) and golimumab (30 patients)). These separated studies necessitated new inclusion procedures (informed consent included) if a patient switched from one TNFi to another. In

2013, we also established a new non-radiographic axial SpA cohort (as follow up to the PREVAS study, 80 patients). In addition, from 2017onwards, patients with axial SpA are treated with other TNFi (certolizumab) and other biologicals, like interleukin 17 inhibitors (secukinumab a.o.) who are not yet included in a cohort study. To enhance long term follow-up, all SpA patients, regardless which type of medication, will be included in the AmSpA cohort. This will prevent repeating informed consent procedures regarding, basically, the same study procedure.

Study objective

To establish one large overarching cohort including all types of SpA (both non-radiographic, radiographic axial SpA and peripheral SpA) regardless of the disease stage and treatment and to longitudinally asses several disease aspects of SpA. The aims of the AmSpA-cohort are:
1) to follow each SpA patient longitudinally and assess the efficacy and possible adverse events of treatment with biologicals (regardless which type) in comparison with biological naive SpA patients. Results will be stratified for gender.
2) to assess the disease course including (radiographic) progression, occurrence of extra-articular manifestations (EAM) (such as anterior uveitis) and comorbidity (such as osteoporosis and cardiovascular disease) and the influence of treatment on the course of these features and comorbidity. Results will be stratified for gender.

Study design

All patients fulfilling the classification of spondyloarthritis according to the ASAS classification criteria and/or modified New York criteria from two Amsterdam Rheumatology immunology Center (ARC) partners, i.e. Reade| Jan van Breemen Institute and the VU University Medical Center will be included. In the future, the Amsterdam Medical Center (AMC), the third ARC partner, will be added to the AmSpA cohort. Patients are followed prospectively according to a clearly defined protocol with regular visits to collect clinical data. During daily clinical practice data on presence of extra-articular disease manifestations, disease activity (BASMI, 44 joint count, MASES, VAS physician, ASDAS), hemodynamic parameters (blood pressure, pulse frequency) and anthropometrical parameters (weight, hip/waist circumference) were collected. In addition, questionnaires on disease activity (BASDAI, VAS pain, patient global disease activity and physical functioning (BASFI) were collected. Radiological assessment will be performed every two years in case of biological use in non-radiographic SpA patients and every 5 years in patients without biological treatment and AS patients. Measurement of bone mineral density (DEXA scans) will be performed every 5 years. Additionally, for study purpose, three questionnaires (wellbeing, health care consumption and work participation) and biobanking every year were collected. All test will be performed by a

physician or a research nurse.

Study burden and risks

The additional *burden* for the patient consists of an extra blood sample obtained during routine patient care and three additional questionnaires. The other mentioned parameters were obtained during routine daily clinical practice in the rheumatology departments. *

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion criteria:

-* diagnosis of axial or peripheral spondyloarthritis, according to the:
o the modified New York criteria OR
o the ESSG criteria OR
o the ASAS classification criteria, including axial as well as peripheral SpA
* signed informed consent

Exclusion criteria

Unable to understand the study aims and methods;Remark: For patients initiating a biological, a treatment selection in daily clinical practice on contra-indications described in the Dutch national guidelines for initiation of a biological treatment, were taken into consideration, especially considering females. An exception is made for treatment with certoluzimab, which can be continued during late gestation and during breastfeeding

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2018
Enrollment:	1000
Type:	Anticipated

Ethics review

Approved WMO

Date:	03-04-2007
Application type:	First submission

Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-11-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-07-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL13486.029.06