Biological and clinical features in preclinical and (very) early spondyloarthritis

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1) To detect undiagnosed clinical SpA in First degree relatives (FDRs)2) To identify biomarker alterations in subclinical SpA3) To investigate prospectively which individuals will develop clinical SpA over time and correlate that to the baseline...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON54532

Source
ToetsingOnline

Brief title
Pre-SpA

Condition

- Autoimmune disorders
- Joint disorders

Synonym
Bechterew, Spondyloarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Reumafonds

Intervention

Keyword: - Biomarkers, - Relatives, - Spondyloarthritis

Outcome measures

Primary outcome

Identify and validate biomarkers which can give more insight in the

pathofysiology and (early) diagnosis of SpA

Secondary outcome

Create a biobank with biological samples and clinical data to find new

biomarkers in SpA patients with future techniques.

Study description

Background summary

Spondylarthropathy (SpA) is second most common form of chronic inflammatory arthritis. It affects young adults between 20-40 years of age. This disease can lead to impairement in daily activity, due to inflammation of the peripheral and axial joints, ankylosis and joint erosions. Due to insidious onset, early symptoms are often missed, leading to a diagnostic delay of more than 10 years. Thanks to the early referral strategies and the introduction of MRI, this delay is reduced to 5-6 years, however, this is still far too long.
Therefore we would like to apply and integrate all knowledge of this disease on early SpA, to healthy individuals at risk of developing SpA. Therefore we chose to look into first degree relatives (FDRs) since we know that the recurrence risk is much higher than non relatives. An HLA-B27 positive FDR has a recurrence risk of 30-40%.

Study objective

1) To detect undiagnosed clinical SpA in First degree relatives (FDRs)
2) To identify biomarker alterations in subclinical SpA
3) To investigate prospectively which individuals will develop clinical SpA over time and correlate that to the baseline clinical and biological features

Study design

-Observational prospective cohort of 5 years, where FDRs are followed up yearly for 5 years.

Study burden and risks

- A total of 6 study visits are planned in five years. An seperate MRI date will be planned if we are not able to perform MRI on same date as first appointment. If participants have complaints (back pain, arthritis), an extra unscheduled visit will be planned and maybe another MRI will take place in case of back pain >3 months. - A questionnaire will be held during each visit, with a duration of 15 minutes, containing questions about complaints and impairments. - A total of 6x blood will be drawn (and also extra time during an unscheduled visit, if applicable). The total amount of blood drawn at first visit will be around 48 mL (9 tubes) and for the other visits 24 mL per visit (5 tubes). - Three times during the study, X-rays will be made of Barsony, lumbar and cervical spine. The total radiation amount is 4.6 mSv. In case of an unscheduled visit (new back pain >3 months) extra series will be made, which lead to a total radiation amount of 6.9 mSv.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- First degree relative of an HLA-B27 positive Ankylosing Spondylitis (Bechterew) patient
- Age at inclusion 18-40 years

Exclusion criteria

- Established diagnosis of sponyloarthritis
- Concomitant conditions that impact participation

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-03-2013
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO

Date:	17-12-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-01-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-10-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-02-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-03-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-07-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-10-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.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	NL41248.018.12