Evaluation of co-morbidities in spondyloarthritis: the ASAS/COMOSpA study The Netherlands

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON38984

Source
ToetsingOnline

Brief title
COMOSpA NL

Condition

- Joint disorders

Synonym
SpA, spondylarthritis, spondylarthropathy

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Assessment of SpondyloArthritis international Society (ASAS)

Intervention

Keyword: co-morbidity, riskfactors, spondyloarthritis

Outcome measures

Primary outcome

Assessment of the prevalence of co-morbidities in SpA

Secondary outcome

na

Study description

Background summary

The term spondyloarthritis (SpA) refers to a group of several related but phenotypically distinct inflammatory rheumatics disorders such as psoriatic arthritis, arthritis related to inflammatory bowel disease, reactive arthritis, a sub-group of juvenile chronic arthritis and ankylosing spondylitis. Whatever the clinical presentation (e.g. axial or peripheral), these diseases can be recognized according to recently available sets of criteria of the Assessment of SpondyloArthritis international Society (ASAS). Apart from the risk of suffering from musculoskeletal or extra-articular complications directly related to their rheumatic disease, SpA patients may also be at increased risk of suffering from other diseases called co-morbidities.

Study objective

The main objective of the study is to assess the prevalence of co-morbidities (e.g. cardiovascular diseases, infections, malignancies and osteoporosis) in SpA. The other objectives are to evaluate the predisposing factors of co-morbidities (e.g. clinical phenotype of the disease or type of treatment) and evaluate if current available recommendations regarding detection and prevention of co-morbidities are being used in clinical practice.

Study design

Investigator initiated, observational, cross-sectional, multi-centre study

Study burden and risks

All participations will have one study visit. During the visit the study questionnaire will be completed, a physical examination will be done and a venous blood sample of approximately 20ml will be taken. Prior to the visit, participants will be asked to complete a part of the study questionnaire at home. There are no risks associated with participation in the study

Contacts

Public
Assessment of SpondyloArthritis international Society (ASAS)

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Leiden 2333 ZA
NL
Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-Adult (older than 18 years of age)
-Classified as spondyloarthritis (SpA) according to the ASAS criteria (either axial or peripheral) --Able to answer the questionnaires
-Able to give a written informed consent after reading and understanding the letter of information.

Exclusion criteria

patients not meeting ASAS axial spondyloarthritis criteria or ASAS peripheral spondyloarthritis criteria

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-06-2013
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	24-04-2013
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL43250.058.13