Efficacy of Statin Therapy on Atherosclerotic Inflammation in Patients with Ankylosing Spondylitis

Published: 15-08-2013
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To evaluate anti-inflammatory effects of statin therapy on vessel wall inflammation by means of FDG PET/CT in AS patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON40566

Source
ToetsingOnline

Brief title
AStatin

Condition

- Autoimmune disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Atherosclerosis, Bechterew

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Ankylosing Spondylitis, Cardiovascular risk, Inflammation, Statin

Outcome measures

Primary outcome

- Effect of 3 months statin therapy on vessel wall FDG uptake.

Secondary outcome

- Medical history, medication use, prior use of DMARD*s and biologicals

- Demographic parameters (age, race, gender)

- Cardiovascular risk factors

- Inflammatory parameters: CRP, hsCRP, BSE, IL1, Il6, TNF, IL17

Study description

Background summary

Ankylosing Spondylitis (AS) is a systemic inflammatory disease characterized by axial joint involvement, sacroiliitis and various extra-articular manifestations. It has been suggested that atherogenesis may be enhanced in AS. The inflammatory process in the vessel wall, comprising atherosclerosis, may be amplified by the presence of a systemic inflammation state in AS. In line with other patients with increased cardiovascular risk, AS patients may benefit from statin therapy by virtue of reduced vessel wall inflammation, thereby also decreasing their risk of cardiovascular events.

Study objective

To evaluate anti-inflammatory effects of statin therapy on vessel wall inflammation by means of FDG PET/CT in AS patients.

Study design

This is a multi-centre intervention study. At baseline a PET/CT will be performed. All AS patients will be enrolled and treated for 3 months with statin therapy, after which PET/CT will be repeated.

Intervention

All AS patients will receive statin therapy after baseline imaging. Statin therapy will consist of a once daily dose of 40 mg Atorvastatin.

Study burden and risks

The study consists of 2 study visit and 3 scheduled telephonic appointments. Patients will undergo 2x FDG PET/CT scan (2 hour) and 2x venapuncture will be performed to withdraw (25 ml blood for every visit, 50ml for total study duration).

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

Subjects with AS
- Age: *18 years
- Diagnosis of AS (following the 1984 Modified New York Criteria for ankylosing Spondylitis (16)) + disease duration since start of first symptoms for a period of more than 3 years.

Exclusion criteria

Subjects may not enter this study if they meet the following criteria
-BMI > 30.
-history of diabetes mellitus/insulin use
-hypertension/use of blood pressure lowering medication
-use of statins or contraindications for the use of statins
-history of cardiovascular events
-proven or suspected bacterial infections.
-use of anti-inflammatory medication from group "biologicals"

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-02-2014
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Atorvastatin

Generic name:	Atorvastatin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	15-08-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-01-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-10-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-12-2014
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
EudraCT	EUCTR2013-002860-19-NL
CCMO	NL45456.018.13