Effect of Tocilizumab on subclinical arterial inflammation and stiffness in patients with active rheumatoid arthritis (DAS28 > 3.2)

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To investigate the effect of anti-IL6 therapy with tocilizumab on subclinical arterial inflammation (endothelial dysfunction) and stiffness in patients with treatment resistant rheumatoid arthritis at baseline and after 6 months treatment

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

Summary

ID

NL-OMON40306

Source
ToetsingOnline

Brief title
tocilizumab and arterial stiffness in RA

Condition

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

Synonym
atherosclerosis in rheumatoid artritis patients

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Atherosclerosis, Pulse wave velocity, Rheumatoid artritis, Tocilizumab

Outcome measures

Primary outcome

Influence of disease activity on arterial stiffness as measured by pulse wave velocity in RA patients receiving tocilizumab

Secondary outcome

Pulse Wave Analysis (PWA) measuring central blood pressure (CBP) and augmentation index (AIx) , using Sphygmocor apparatus, effect on skin autofluorescence as a marker for tissue AGE accumulation and measuring endothelial progenitor cells (EPC's) and serum endothelial activation markers such as thrombomodulin (TM), soluble vascular cell adhesion molecule-1 (sVCAM-1), and von Willebrand factor (vWF) , and Lipopolysaccharide (LPS) stimulated cytokine (IL-1β, IL-6, IL-8, IL-10 and TNF-α) production in peripheral blood mononuclear cells. Throughout the study, medication and other influencing factors of endothelial dysfunction will be kept as steady as possible. Changes in traditional risk factors as smoking, hypertension, use of antihypertensive drugs or dyslipidemia and BMI will be recorded.

Study description

Background summary

RA is an independent risk factor for the development of cardiovascular disease (CVD). Biological and non-biological DMARDS that suppress systemic inflammation have also been shown to decrease cardiovascular disease risk. It is however unclear which inflammatory mechanisms contribute to the specific atherosclerotic complication of RA. We therefore want to investigate the effect of anti-IL6 therapy with tocilizumab (TCZ) on subclinical arterial inflammation and stiffness in patients with active rheumatoid arthritis with an indication for TCZ treatment.

Study objective

To investigate the effect of anti-IL6 therapy with tocilizumab on subclinical arterial inflammation (endothelial dysfunction) and stiffness in patients with treatment resistant rheumatoid arthritis at baseline and after 6 months treatment

Study design

observational study

Study burden and risks

Before start of the study and at 6 months 50ml of blood extra will be drawn beside the routine blood samples for RA.
Secondly, patients will have measurements of arterial stiffness, AGE accumulation at the vascular department. Measurements of arterial stiffness and AGE accumulation are usually well tolerated and non-invasive, but do take time from the patient and patients have to be fasting in the morning of the measurements.

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

• Patients fulfilling the American College of Rheumatology criteria for RA at diagnosis
• Active RA; DAS-28 score > 3.2
• Indication for treatment with tocilizumab.
• Female/male patients 18-80 years of age.
• Mentally able to understand the written information and to make the decision to participate.
• Written Informed consent

Exclusion criteria

• Pregnancy
• Insulin dependent Diabetes Mellitus
• Renal impairment (eGFR <30ml/min)
• MI or sepsis in the past three months
• Unable to lay flat for 30-45 minutes for the PWV measurement

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-02-2015
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	18-12-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL46764.042.14
Other	volgt