Influence of everolimus on atherosclerosis in RA.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28147

Source
NTR

Brief title
Influence of everolimus on premature atherosclerosis in RA patients

Health condition

Rheumatoid arthritis, endothelial activation, endothelial dysfunction, intima media thickness, cardio-vascular disease, everolimus

Sponsors and support

Primary sponsor: Novartis
UMC Groningen
Source(s) of monetary or material Support: Novartis

Intervention

Outcome measures

Primary outcome

1. Endothelial activation as measured by von Willebrand factor, soluble vascular adhesion molecule, thrombomodulin;

2. Endothelial dysfunction as measured by small artery elasticity;

3. Premature atherosclerosis as measured by intima media thickness.

Secondary outcome

1. Effect of everolimus on RA;

2. Drop-out due to side effects of everolimus.

Study description

Background summary

N/A

Study objective

Cardio-vascular disease is increased in RA. Everolimus has shown to have beneficial effects on endothelial function in cardiac tranplant patients and renal transplant patients. We want to study the effect of everolimus in patients with active RA.

Study design

All parameters are measured at t=0 and t= 6 months.

Intervention

Patients are treated with everolimus for six months, target plasma concentration of everolimus 6-10 ng/ml.

Contacts

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Eligibility criteria

Inclusion criteria

1. Fulfill the American College of Rheumatology criteria for RA;

2. DAS-28 score>3,2;

3. Female/male patients 18-80 years of age;

4. Mentally able to understand the written information and to make the decision to participate;

5. Informed consent.

Exclusion criteria

1. Pregnancy or breastfeeding status;

2. Diabetes mellitus (fasting blood glucose =/> 7.0 mmol/L);

3. Renal impairment (eGFR <60ml/min);

4. Recent Surgery;

5. MI or sepsis in the past three months.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2010
Enrollment:	15
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-06-2010
Application type:	First submission

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
NTR-new	NL2249
NTR-old	NTR2376
CCMO	NL27732.042.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A