Tumor Necrosis Factor blockade in patients with Rheumatoid Arthritis inhibits Atherothrombosis.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29079

Source
NTR

Brief title
TUNDRA

Health condition

Rheumatoid Arthritis

Sponsors and support

Primary sponsor: Academic Medical Center
Amsterdam, the Netherlands

Intervention

Outcome measures

Primary outcome

1. Endothelial Function (FMD);

2. Glycocalyx;

Before treatment, 0-4 weeks after treatment, 9-12 weeks after treatment.

Secondary outcome

1. Atherosclerosis:

Plasma: Total cholesterol, LDL, HDL, Triglycerides, Lp(a), ox-LDL;

2. Thrombosis:

D-dimer, F1+2, sTF, PAI-I;

3. Inflammation:

IL-1beta, TNF-alpha, IL-6, IL-8, IL-10, hsCRP.
Before treatment, 0-4 weeks after treatment, 9-12 weeks after treatment.

Study description

Background summary

Rationale:

Rheumatoid arthritis is associated with an increased incidence of atherosclerotic vascular disease. It is suggested that systemic inflammation is a risk factor for enhanced atherogenesis which is for instance also observed in SLE. In line with this, TNF-alpha is a central mediator of inflammation in RA and inhibition thereof may exert anti-atherothrombotic effects.

Objective:

In the current study we aim to establish whether TNF-alpha plays a central role in inflammation-mediated acceleration of atherogenesis and the propencity towards development of atherothrombotic disease in RA.

Study design:

This is an observational study in RA patients undergoing therapy with TNF-alpha blockade. Prior to receiving treatment surrogate markers for atherosclerosis, thrombosis, inflammation and angiogenesis will be assessed. These measurements will be repeated to evaluate short-term and long-term effects.

Study population:

We will include RA patients who are experiencing an inflammatory exacerbation of RA and who will be treated with TNF-alpha blockade.

Main study parameters:

Surrogate markers for atherosclerosis (endothelial function, glycocalyx), thrombosis (PMC, plasma markers), inflammation and angiogenesis (plasma markers).

Nature and extent of the burden and risks associated with participation, benefit and group telatedness: This is an observational study evaluating additional benefits (anti-atherothrombotic effects) of standard clinical practice (TNF-alpha blockade). Measurement of endothelial function and glycocalyx volume are routinely performed at the department of vascular medicine.

Study objective

In the current study we aim to establish whether TNF-alpha plays a central role in inflammation-mediated acceleration of atherogenesis and the propencity towards development of atherothrombotic disease in RA.

Study design

N/A

Intervention

TNF-alpha blockade.
(patients are their own control)

Contacts

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Eligibility criteria

Inclusion criteria

1. Male or female patients who were priorly diagnosed with RA, who are currently experiencing an inflammatory episode and who will be treated with TNF-alpha blockade;

2. Age 18-80 years.

Exclusion criteria

1. Patients who were priorly diagnosed with diabetes, hypertension or cardiovascular disease;

2. Current signs or symptoms of severe, progressive or uncontrolled hepatic, haematological, gastroenterological, endocrine, pulmonary, cardiac or neurological disease.

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2006
Enrollment:	15
Type:	Actual

Ethics review

Positive opinion Date:	12-12-2006
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	NL824
NTR-old	NTR837
Other	: N/A
ISRCTN	ISRCTN26286159

Study results

Summary results
N/A