

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

Gepubliceerd: 12-12-2006 Laatste bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29079

Bron

Nationaal Trial Register

Verkorte titel

TUNDRA

Aandoening

Rheumatoid Arthritis

Ondersteuning

Primaire sponsor: Academic Medical Center
Amsterdam, the Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Endothelial Function (FMD);

2. Glycocalyx;

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

Toelichting onderzoek

Achtergrond van het onderzoek

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 propensity 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 relatedness: 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.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Academic Medical Center (AMC), Department of Vascular Medicine, room F4-159.2,
P.O. Box 22660
Sander Leuven, van
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5668675

Wetenschappelijk

Academic Medical Center (AMC), Department of Vascular Medicine, room F4-159.2,
P.O. Box 22660
Sander Leuven, van
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5668675

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2006
Aantal proefpersonen:	15
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum: 12-12-2006

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL824
NTR-old	NTR837
Ander register	: N/A
ISRCTN	ISRCTN26286159

Resultaten

Samenvatting resultaten

N/A