

TUmor Necrosis factor blockaDe in patients with Rheumatoid Arthritis inhibits atherothrombosis

Submission date 16/01/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 16/01/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 16/01/2007	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Acronym

TUNDRA

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

This is an observational study in RA patients undergoing therapy with TNF-alpha blockade

Primary study design

Observational

Secondary study design

Single-centre

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Rheumatoid arthritis

Interventions

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

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Endothelial Function (Flow-Mediated Dilation [FMD])
2. Glycocalyx

Before treatment, zero to four weeks after treatment, nine to 12 weeks after treatment.

Secondary outcome measures

1. Atherosclerosis: Plasma:
 - a. total cholesterol
 - b. Low Density Lipoproteins [LDL]
 - c. High Density Lipoproteins [HDL]
 - d. Triglycerides
 - e. Lipoprotein a [Lp(a)]
 - f. oxidised LDL
2. Thrombosis:
 1. D-dimer
 2. prothrombin fragment 1 and 2 (F1+2)
 3. soluble Tissue Factor (sTF)
 4. Plasminogen Activator Inhibitor type 1 (PAI-1)
3. Inflammation:
 - a. InterLeukin-1beta (IL-1beta)
 - b. TNF-alpha
 - c. InterLeukin 6 (IL-6)
 - d. InterLeukin-8 (IL-8)
 - e. Interleukin 10 (IL-10)
 - f. high-sensitivity C-Reactive Protein (hsCRP)

Before treatment, zero to four weeks after treatment, nine to 12 weeks after treatment.

Overall study start date

01/01/2006

Completion date

31/12/2007

Eligibility

Key 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 to 80 years

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

15

Key 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

Date of first enrolment

01/01/2006

Date of final enrolment

31/12/2007

Locations**Countries of recruitment**

Netherlands

Study participating centre

Academic Medical Center (AMC)

Amsterdam

Netherlands

1100 DD

Sponsor information**Organisation**

Academic Medical Center (AMC) (The Netherlands)

Sponsor details

P.O. Box 22660

Amsterdam

Netherlands

1100 DD

Sponsor type

Hospital/treatment centre

Website

<http://www.amc.uva.nl/#http://www.amc.uva.nl/>

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Academic Medical Center (AMC) (The Netherlands)

Alternative Name(s)

Academic Medical Center, AMC

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

Netherlands

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration