TUmor Necrosis factor blockaDe in patients with Rheumatoid Arthritis inhibits atherothrombosis

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number 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 propencity 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

Study type(s)

Treatment

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(s)

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

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

Key secondary outcome(s))

- 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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Not Specified

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration