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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

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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 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

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
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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