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T-cell Inhibition by Mycophenolate Mofetil Treatment in Patients Undergoing Carotid Endarterectomy

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	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/11/2010	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
Time To Care

Study objectives
T-cell inhibition with Mycophenolate Mofetil (MMF) attenuates T-cell number, T-cell activation and T-cell monocyte interaction, thereby minimising the T-cell-driven inflammatory amplification loop. The latter will contribute to improvement of anti-atherogenic defence mechanisms, such as improvement of endothelial function and attenuation of the pro-inflammatory state.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, placebo controlled, parallel group, double blinded trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Vascular disease

Interventions
Participants will be randomised to either treatment with mycophenolate mofetil (MMF) or placebo.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Mycophenolate mofetil (MMF)

Primary outcome measure
After three weeks of treatment: immunostaining for: CD3, CD4, CD8, CD40L, CD69, CD86.

Secondary outcome measures
After three weeks of treatment: immunostaining for endothelial, plaque composition and stability markers.

Overall study start date
01/06/2006

Completion date
01/01/2008

Eligibility

Key inclusion criteria
Consecutive patients with carotid artery stenosis (more than 70% diameter stenosis on angiography or ultrasonography) with ipsilateral Transient Ischaemic Attack (TIA) who are planned to undergo Carotid EndArterectomy (CEA) will be included and treated for a minimum of three weeks prior to surgery. These patients will be recruited at the outpatient department of Vascular Surgery.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
50

Key exclusion criteria
Patients who are unable to tolerate MMF treatment, who withdraw their consent or those with any other medical condition or laboratory abnormality which in the opinion of the principal investigator could affect subject safety, preclude evaluation of response, or render unlikely that the patient would complete the study, are excluded.

Date of first enrolment
01/06/2006

Date of final enrolment

01/01/2008

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2010		Yes	No