

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

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 04/11/2010	Condition category Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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)

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 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