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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

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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 |