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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21023

Source
NTR

Brief title
TimeToCare

Health condition

Atherosclerotic vascular disease of the carotid artery

Sponsors and support

Primary sponsor: Academic Medical Center
Amsterdam, the Netherlands

Intervention

Outcome measures

Primary outcome

After 3 weeks of treatment: Immunostaining for: CD3, CD4, CD8, CD40L, CD69, CD86.

Secondary outcome

After 3 weeks of treatment: Immunostaining for endothelial, plaque composition and stability markers

Study description

Background summary

Patients with carotid artery stenosis undergoing endarterectomy will be randomized to either placebo or MMF treatment. Prior to scheduled surgery baseline measurements will be assessed and patients will start study medication. One week prior to surgery a second study will take place and measurements will be repeated. At time of surgery endarterectomy specimens will be collected for immunostaining to evaluate T-cell and monocyte/macrophage numbers and activation status as well as effects on endothelial and smooth muscle cells on atherosclerotic plaque composition.

Study objective

T-cell inhibition with Mycophenolate Mofetil (MMF) attenuates T-cell number, T-cell activation and T-cell – monocyte interaction, thereby minimizing 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.

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

Consecutive patients with carotid artery stenosis (>70% diameter stenosis on angiography or ultrasonography) with ipsilateral transient ischemic 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.

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2006

Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion Date:	15-12-2006
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL828
NTR-old	NTR841
Other	: N/A
ISRCTN	ISRCTN84092396

Study results

Summary results
N/A