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

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21023

Bron
Nationaal Trial Register

Verkorte titel
TimeToCare

Aandoening

Atherosclerotic vascular disease of the carotid artery

Ondersteuning

Primaire sponsor: Academic Medical Center
Amsterdam, the Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2006
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	15-12-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

N/A