

Novel maintenance Immunosuppression with Controlled systemic Exposure.

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To compare the safety, efficacy, and impact on non-immune toxicity of AUC-controlled withdrawal of either cyclosporin (Neoral) or MMF (Cellcept) in stable renal transplant recipients currently on a triple maintenance regimen with Neoral, MMF, and...

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

Samenvatting

ID

NL-OMON27195

Bron

NTR

Verkorte titel

NICE

Aandoening

Stable renal transplant recipients.

Ondersteuning

Primaire sponsor: Roche, Novartis

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Composite of Graft function,
- incidence of acute rejection episodes;

2. Graft and patient survival.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

To compare the safety, efficacy, and impact on non-immune toxicity of AUC-controlled withdrawal of either cyclosporin (Neoral) or MMF (Cellcept) in stable renal transplant recipients currently on a triple maintenance regimen with Neoral, MMF, and steroids.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Randomized, controlled, prospective multicenter study in stable renal transplant recipients, at least 6 months post-transplantation, who receive maintenance immunosuppressive treatment with cyclosporine (Neoral) b.i.d., mycophenolate mofetil (MMF) 1 gram b.i.d., and steroids.

In eligible patients, systemic drug exposure (cyclosporine, MMF) will be measured by a 12-hours area under the time-blood concentration curve (AUC0-12) before randomization to one of the three study arms.

Patients will be randomized 1:1:1 with stratification for the occurrence of previous acute rejection episodes.

- Group A will continue on their current treatment regimen aiming at C2 levels of 700 ng/ml, (range: 600-800 ng/ml) In this group AUC-values will be blinded to the clinicians and evaluated retrospectively.

- In group B (MMF withdrawal) cyclosporine will be dosed to reach the defined target AUC0-12 of 3250 ng.h/ml (range 3000-3500 ng.h/ml).

- In group C (cyclosporine withdrawal) MMF will be given at a fixed dose of 1000 mg b.i.d at the start of the study period. After cessation of the cyclosporine AUC will be measured to adjust the dose to reach the defined MPA-AUC0-12 target of 75 mg.h/ml (range 60-90 ng.h/ml).

For safety reasons the minimal dose will be 500 mg b.i.d.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients, 18 years or older, on maintenance therapy with Neoral, MMF and steroids;
2. Informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Calculated creatinine clearance $\leq$ 20 ml/min;
2. Multi-organ recipients;
3. Patients with an (historic) PRA $>60\%$;

4. Vascular type rejection in the past;
5. Patients with more than two acute rejection episodes in the past;
6. Third renal transplant or more;
7. Patients receiving other investigational drugs than MMF in combination with Neoral;
8. Metastatic neoplasms, post-transplant lymphoproliferative disease.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2003
Aantal proefpersonen:	100
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	15-09-2005
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	NL440
NTR-old	NTR480
Ander register	: N/A
ISRCTN	ISRCTN81895822

Resultaten

Samenvatting resultaten

N/A