Novel maintenance Immunosuppression with Controlled systemic Exposure.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27195

Source
Nationaal Trial Register

Brief title
NICE

Health condition

Stable renal transplant recipients.

Sponsors and support

Primary sponsor: Roche, Novartis

Intervention

Outcome measures

Primary outcome

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

2. Graft and patient survival.

Secondary outcome

Non-immune toxicity

1. Hypertension;

2. Hyperlipedimia;

3. Gout, uric acid;

4. Magnesium;

5. Nausea, dyspepsia, diarrhea;

6. Anemia/Leukopenia/Thrombopenia;

7. Infections (clinically defined);

8. Post-transplant lympho-proliferative disease;

9. Malignancy.

Study description

Background summary

N/A

Study objective

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.

Study design

N/A

Intervention

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 elegible 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.

Contacts

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Eligibility criteria

Inclusion criteria

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

2. Informed consent.

Exclusion criteria

1. Calculated creatinine clearance £ 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 lymfoproliferative disease.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2003

Enrollment:	100
Type:	Actual

Ethics review

Positive opinion Date:	15-09-2005
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	NL440
NTR-old	NTR480
Other	: N/A
ISRCTN	ISRCTN81895822

Study results

Summary results
N/A