Safety and efficacy of mycophenolate mofetil in pediatric renal transplantation.

No registrations found.

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

Summary

ID

NL-OMON29296

Source
Nationaal Trial Register

Brief title
N/A

Sponsors and support

Primary sponsor: N/A
Source(s) of monetary or material Support: Dutch Kidney Foundation.

Intervention

Outcome measures

Primary outcome

1. Glomerular filtration rate;

2. Incidence of acute rejections;

3. Serumlipids;

4. Bloodpressure and number of antihypertensive drugs.

Secondary outcome

1. Graft survival;

2. Incidence of malignancies;

3. Incidence of viral infections;

4. Incidence of anemia.

Study description

Background summary

Mycophenolate mofetil (MMF) has gained a place in the immunosuppressive treatment of kidney transplantation, either added to a regimen of corticosteroids and cyclosporine, or replacing azathioprine in the triple regimen corticosteroids, cyclosporine and azathioprine. Its introduction has reduced the incidence of acute rejection episodes, both in adults and in children. Besides, it considerably improved short-term graft survival in children in the Netherlands. The side-effects are relatively mild, in the gastrointestinal system; it has no known negative effects on blood vessels or lipids. In contrast, cyclosporine (CsA) negatively affects the cardiovascular system and the kidneys: it causes vasoconstriction with elevation of blood pressure, nephrotoxicity, and corroborates the dyslipidemia caused by corticosteroids. Furthermore its use produces cosmetic changes, which may induce non-compliance, especially in adolescent girls. We felt it would be better, therefore, to restrict cyclosporine treatment to the first year after transplantation. This study aims at prospective assessment of the long-term safety and efficacy of MMF as an immunosuppressive drug in the maintenance phase of pediatric kidney transplantation as compared to cyclosporine, both in combination with corticosteroids.

Methods:

50 pediatric patients with a kidney graft, until the end of the 1st year treated with corticosteroids, MMF and CsA, with maximally 1 steroid sensitive acute rejection episode during the 1st year, are randomized to 2 groups: withdrawal of MMF or of CsA over 3 months. At the end of the 2nd and 3rd year after transplantation the following endpoints are compared between the groups: as primary endpoints the glomerular filtration rate and the number of acute rejection episodes, changes in serum lipids, blood pressure, and as secondary endpoints patient and graft survival, prevalence of anemia, incidence of infectious diseases and of malignancies.

Study objective

1. MMF/Prednisolone is as efficacious in prevention of acute rejections as cyclosporine (CsA)/Pred;

2. MMF/Prednisolone is safer than CsA/Pred, in renal function, lipids, and blood pressure.

Study design

N/A

Intervention

Start trial is one year after transplantation.

Randomisation between 2 groups:

continuing with MMF/Pred or CsA/Pred by withdrawal over 3 months of the 3rd immunosuppressive drug. During the 3 months of withdrawal the Predniolone dosage is doubled. Follow-up is 2 years.

Contacts

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Eligibility criteria

Inclusion criteria

All Dutch children, receiving a first kidney transplant after 01-01-2000, treated with initial immunosuppression corticosteroids, MMF and CsA, during the latter part of the study with addition of basiliximab.

Exclusion criteria

1. Not on triple therapy (Pred/CsA/MMF) at the end of the 1st year;

2. More than one acute rejection episode;

3. Rejection episode being not steroid sensitive;

4. No written informed consent.

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):	01-01-2000
Enrollment:	44
Type:	Actual

Ethics review

Positive opinion

Date:	30-10-2006
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	NL788
NTR-old	NTR800
Other	: N/A
ISRCTN	ISRCTN89278733

Study results

Summary results
Transplantation. 2007 Apr 27;83(8):1041-7.