

Randomised multi-centre study comparing mycophenolate and ciclospoine A in children with a frequent relapsing or corticoid dependent idiopathic nephrotic syndrome.

No registrations found.

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

Summary

ID

NL-OMON22419

Source

NTR

Brief title

N/A

Health condition

Children with frequent relapsing or corticoid dependent minimal change nephrotic syndrome.

Sponsors and support

Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

GFR.

Secondary outcome

1. Relapse rate;
2. Other adverse effects.

Study description

Background summary

Children with frequently relapsing or steroid dependent nephrotic syndrome are currently treated with daily ciclosporine. Because of serious side effects of ciclosporine, as nephrotoxicity and hypertension, an alternative treatment is investigated. To compare the efficacy and safety of mycophenolate mofetil in these children, we randomise children <17 years, with frequently relapsing or steroid dependent minimal change nephrotic syndrome, for daily treatment with ciclosporine (5mg/kg/day) or mycophenolate mofetil (1200mg/m²/day) during 1 year. Side effects and number of relapses of the nephrotic syndrome are compared between the two groups.

Study objective

Mycophenolate mofetil is effective in preventing relapses of the nephrotic syndrome and has less nephrotoxic effects compared to ciclosporine A.

Study design

N/A

Intervention

Randomisation for mycophenolate or ciclosporine A.

Contacts

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Eligibility criteria

Inclusion criteria

1. Children <18 years;
2. Minimal change nephrotic syndrome
GFR >80 ml/1.73m²/min;
3. Steroid dependency or frequent relapsing.

Exclusion criteria

1. Severe anemia or leucopenia;
2. Active infection;
3. Failure of ciclosporine treatment in history.

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):	01-12-2002
Enrollment:	31
Type:	Actual

Ethics review

Positive opinion	
Date:	10-11-2005
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	NL461
NTR-old	NTR502
Other	: N/A
ISRCTN	ISRCTN86423228

Study results

Summary results

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