Optimal treatment of steroid sensitive nephrotic syndrome in children.

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Spreading the same cumulative dose of corticosteroids over a longer period of time will lower the number of patients with frequent relapses in steroid sensitive nephrotic syndrome in children.

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

Samenvatting

ID

NL-OMON27512

Bron
NTR

Verkorte titel
N/A

Aandoening

-children with the initial episode or five or less relapses will be included
-only children with a history of an idiopathic NS/MCNS will be included

Ondersteuning

Primaire sponsor: Dutch Kidney Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Number of patients with frequent relapses.

Toelichting onderzoek

Achtergrond van het onderzoek

The aim of the study is to optimize treatment duration of corticosteroid therapy for steroid sensitive nephrotic syndrome (SSNS) in children.
Clinical outcome in terms of relapse rate and the occurrence of frequent relapses in SSNS seems to depend on the duration of initial corticosteroid treatment. In the Netherlands, standard treatment of the initial episode consists of 3 months corticosteroid therapy.
Hodson et al. published a Cochrane meta-analysis comprising all randomized controlled trials concerning treatment duration and dose of corticosteroids in the treatment of the nephrotic syndrome. This meta-analysis showed that clinical outcome is determined by treatment duration rather than dose. The number of patients with frequent relapses was found to be lower when treatment was prolonged from 2 to 3 months (OR 0.63, 95% CI 0.46-0.84).
In addition, the authors calculated that within a population with an expected relapse rate of 68% after two months of steroid treatment, the relapse rate will fall by 7.5% for every month by which the duration of therapy is prolonged. According to this calculation, further prolongation of the treatment from 3 to 6 months would reduce the expected relapse rate from 61% to 39%. However additional research was needed to confirm the benefit of 6 months versus 3 months corticosteroid therapy.
In a national multicentre, randomised, placebo controlled trial we will compare 6 months (24 weeks) versus 3 months (12 weeks) of corticosteroid therapy for the initial episode of idiopathic nephrotic syndrome. In both groups an equal cumulative dose of 3400 mg/m2 prednisolone is administered.
After a follow up period of 2, resp. 5 years, primary and secondary outcome will be evaluated in an intention-to-treat analysis. Power analysis regarding the primary outcome indicates that a decrease in the number of patients with frequent relapses from 72% to 48% will reach statistical significance with n=75 patients in each treatment group. The statistical analysis will be supported by the department of medical statistics of the Erasmus Medical Centre in Rotterdam. Scientific director is Dr. J. Nauta, head of the children’s nephrology department at the Sophia Children’s Hospital in Rotterdam.

Doel van het onderzoek

Spreading the same cumulative dose of corticosteroids over a longer period of time will lower the number of patients with frequent relapses in steroid sensitive nephrotic syndrome in children.

Onderzoeksproduct en/of interventie

Prednisolone therapy.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Children from 9 months up to 16 years will be included;

2. Only children with idiopathic nephrotic syndrome will be included.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Children with nephrotic syndrome due to a specific disease;

2. Children with more than five relapses;

3. Chilren younger than 9 month or older than 16 years.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2005
Aantal proefpersonen:	150
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	07-09-2005
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	NL218
NTR-old	NTR255
Ander register	: N/A
ISRCTN	ISRCTN27871415

Resultaten

Samenvatting resultaten
N/A