

# Optimal treatment of steroid sensitive nephrotic syndrome in children

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| <b>Submission date</b><br>20/12/2005   | <b>Recruitment status</b><br>No longer recruiting            | <input type="checkbox"/> Prospectively registered    |
|  |  | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>20/12/2005 | <b>Overall study status</b><br>Completed                     | <input type="checkbox"/> Statistical analysis plan   |
|  |  | <input type="checkbox"/> Results                     |
| <b>Last Edited</b><br>25/08/2009       | <b>Condition category</b><br>Urological and Genital Diseases | <input type="checkbox"/> Individual participant data |
|  |  | <input type="checkbox"/> Record updated in last year |

**Plain English summary of protocol**  
Not provided at time of registration

**Study website**  
<http://www.nefrotischsyndroom.nl>

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr N Rijswijk, van

**Contact details**  
Erasmus Medical Centre,  
Sophia Children's Hospital,  
Fellow pediatric nephrology,  
P.O Box 2040  
Rotterdam  
Netherlands  
3000 CA  
+31 (0)10 4636588  
[n.vanrijswijk@erasmusmc.nl](mailto:n.vanrijswijk@erasmusmc.nl)

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

## Secondary identifying numbers

NTR255

# Study information

## Scientific Title

## Study objectives

Spreading the same cumulative dose of corticosteroids over a longer period of time will lower the relapse rate in steroid sensitive nephrotic syndrome in children

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Received from local medical ethics committee

## Study design

Multicentre randomised double blind placebo controlled parallel group trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Minimal Change Nephrotic Syndrome(MCNS), Nephrotic syndrome

## Interventions

Prednisolone therapy

## Intervention Type

Drug

## Phase

Not Specified

## Drug/device/biological/vaccine name(s)

Prednisolone

**Primary outcome measure**

1. Number of patients in remission
2. Number of relapses
3. Number of patients with frequently relapsing nephrotic syndrome

**Secondary outcome measures**

Cumulative dose of prednisolon during follow up

**Overall study start date**

01/01/2005

**Completion date**

31/12/2014

## **Eligibility**

**Key inclusion criteria**

1. Children from 9 months up to 16 years will be included
2. Only children with idiopathic nephrotic syndrome will be included

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

9 Months

**Upper age limit**

16 Years

**Sex**

Both

**Target number of participants**

340

**Key exclusion criteria**

1. Children with nephrotic syndrome due to a specific disease
2. Children with more than five relapses
3. Children younger than 9 months or older than 16 years

**Date of first enrolment**

01/01/2005

**Date of final enrolment**

31/12/2014

# Locations

## Countries of recruitment

Netherlands

## Study participating centre

Erasmus Medical Centre,

Rotterdam

Netherlands

3000 CA

# Sponsor information

## Organisation

Erasmus Medical Centre (Netherlands)

## Sponsor details

Sophia Children's Hospital

Dr. Molewaterplein 60

Rotterdam

Netherlands

3015 GJ

+31 (0)10 4636363

info@nierstichting.nl

## Sponsor type

Hospital/treatment centre

## ROR

<https://ror.org/018906e22>

# Funder(s)

## Funder type

Charity

## Funder Name

Dutch Kidney Foundation (Nierstichting Nederland) (Netherlands)

## Alternative Name(s)

Dutch Kidney Foundation

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

Netherlands

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration