ISRCTN27871415 https://doi.org/10.1186/ISRCTN27871415

Optimal treatment of steroid sensitive nephrotic syndrome in children

Submission date	Recruitment status	[_] Prospectively registered
20/12/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/12/2005	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
25/08/2009	Urological and Genital Diseases	[_] 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

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