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Levamisole treatment for children with steroid sensitive nephrotic syndrome

Submission date	Recruitment status	[_] Prospectively registered
19/05/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/09/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/01/2019	Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.levamisoletrial.com/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ACE080503

Study information

Scientific Title
Levamisole treatment for children with steroid sensitive nephrotic syndrome: a multicentre double-blind placebo-controlled randomised trial

Study objectives
Levamisole prevents the occurence of relapses of nephrotic syndrome and prolongs the time to a relapse in children with frequent relapsing steroid sensitive nephrotic syndrome (SSNS).

Please note that as of 18/02/2013, the anticipated end date for this trial was updated from 15/05/2010 to 28/03/2012

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee of Academic Medical Centre Amsterdam approved on the 6th April 2006

Study design
Multicentre double-blind placebo-controlled randomised clinical trial followed by a cohort study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Nephrotic syndrome

Interventions
Treatment with levamisole/placebo will be started during prednisone treatment for relapse when patient's urine is protein free for 3 to 21 days. Levamisole/placebo will be given orally as tablet in a dose of 2.5 mg/kg on alternate days. In the RCT, the start of levamisole/placebo treatment is considered day 0, treatment will be discontinued when a relapse, necessitating

prednisone treatment occurs or after 12 months. Patients who have a premature withdrawal (relapse) will be followed up for the whole period of 12 months. In the cohort study levamisole treatment will be continued for 12 months unless patients will have more than one relapse in 6 months.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Time to relapse; time between start of the study medication and occurrence of a relapse or, in case of no relapse, time of censoring (12 months after start of trial medication). Only a relapse necessitating prednisone treatment is considered a primary endpoint relapse.

Secondary outcome measures
1. Average quantity in milligrams of steroids administered per month during the study, measured 12 months after randomisation
2. Evaluation whether treatment effect differs with underlying disease process (steroid dependency yes/no), measured 12 months after randomisation
3. Prior use of disease modifying agents (yes/no), measured 12 months after randomisation
4. Maintenance dose prednisone at time of relapse, reported at time of relapse

Overall study start date
15/05/2007

Completion date
28/03/2012

Eligibility

Key inclusion criteria
1. Primary diagnosis: frequently relapsing idiopathic SSNS with or without steroid dependency
2. Aged less than or equal to 18 years (not less than two years), either sex
3. Written Informed Consent

Participant type(s)
Patient

Age group
Child

Upper age limit
18 Years

Sex

Both

Target number of participants
100: 50 placebo, 50 levamisole

Key exclusion criteria
1. Previously treated with Levamisole
2. Unresponsive to cyclosporine or mycophenolate mofetil (MMF)
3. Nephrotic syndrome due to specific kidney diseases
4. Patients with neutropenia, convulsions and hepatic disease
5. Patients with prolongation of the QTc-time on the surface electrocardiogram (greater than 0.44 secconds)
6. Pregnancy, breast-feeding or planned pregnancy during the study
7. Participation in another trial

Date of first enrolment
15/05/2007

Date of final enrolment
28/03/2012

Locations

Countries of recruitment
Belgium

France

India

Italy

Netherlands

Poland

Study participating centre
Academic Medical Centre (AMC)
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Centre (AMC) (Netherlands)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.amc.uva.nl/

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Charity

Funder Name
Dutch Kidney Foundation (Netherlands) (ref: C04.2116)

Alternative Name(s)
Dutch Kidney Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Netherlands

Funder Name
Emma Children's Hospital Foundation (Netherlands)

Funder Name
Foundation Rare Diseases Fund ((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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2018	18/01/2019	Yes	No