

Levamisole treatment for children with steroid sensitive nephrotic syndrome

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jean-Claude Davin

Contact details
Academic Medical Centre (AMC)
Emma Kinderziekenhuis
Department of Paediatric Nephrology
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ
+31 (0)20 566 7919
j.c.davin@amc.nl

Additional identifiers

Protocol serial number
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 occurrence 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

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Upper age limit

18 Years

Sex

All

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 seconds)
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)

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

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes