

# Levamisole treatment for children with steroid sensitive nephrotic syndrome

**Submission date**  
19/05/2009

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
18/09/2009

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
18/01/2019

**Condition category**  
Urological and Genital Diseases

☐ Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www.levamisoletrial.com/>

## Contact information

### Type(s)

Scientific

### Contact name

Dr Jean-Claude Davin

### Contact details

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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 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

## 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 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)

**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?
<a href="#">Results article</a>	results	01/02/2018	18/01/2019	Yes	No