

# Wat is de rol van stress in het veroorzaken van eiwitverlies in de urine bij kinderen met het nefrotisch syndroom?

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON22912

### Source

Nationaal Trial Register

### Brief title

SeNS

### Health condition

idiopathic nephrotic syndrome  
idiopathisch nefrotisch syndroom  
stress

## Sponsors and support

**Primary sponsor:** Academic Medical Center (AMC) / Emma Children's Hospital

**Source(s) of monetary or material Support:** Nierstichting Nederland

## Intervention

## Outcome measures

### Primary outcome

Relapse nephrotic syndrome.

## **Secondary outcome**

N/A

## **Study description**

### **Background summary**

Idiopathic Nephrotic Syndrome is the most frequent glomerular disease in children. Ten percent of patients are steroid resistant and have a high risk to develop end stage renal failure. In the group of steroid sensitive patients about 50 percent will have frequent relapses leading to the prolonged use of high prednisone dosage or to steroid sparing agents such as cyclophosphamide or cyclosporine.

Recently Takahashi and co-workers (2007) have shown that after common cold, the events preceding relapses most frequently were stressful situations. This observation could support the hypothesis of somatic consequences of mental events in idiopathic nephrotic syndrome just as already described in several other immunologically mediated diseases such as SLE, skin diseases, asthma, and inflammatory bowel diseases (Picardi and Abeni, 2001; Mawdsley and Rampton, 2005; Straub et al, 2005; Bricou et al, 2006; Chen and Miller, 2007). Recent progresses in neuroendocrine-immunology give a scientific support to the relation between psychological distress and somatic illness (for a review: Mawdsley and Rampton, 2005).

Parents of children with ISSNS often report the concomitant relation between stress events (inducing excitation or fears) and relapses. They have expressed their frustration towards the lack of attention paid by doctors to their observation. Furthermore, they have asked us to help them in setting up a registry for parents and patients. This has given us the idea to use this registry to the purpose of evaluating in a prospective study what is the role of stress as trigger for relapses.

Each parent / patient will be able to access an electronic diary to register the daily use of medications and the occurrence of stressful events e.g. start of school, school examination, anniversary, visit to the dentist or the pediatrician, death of a relative. In addition proteinuria will be measured daily using Albustix. Using statistical analysis we will investigate if there is a temporal concentration of relapses of disease around stressful events.

In case this pilot study will demonstrate a temporal relation between stress events and relapses, further investigations (using questionnaire on child vulnerability, overprotection and parental stress) will be set up to study psychological features of the patient and his family in order to define criteria allowing to trace patients with high sensibility to stress. This will allow preventive training for coping with stress of patients and their families who need it. Finally, the confirmation of the triggering effect of stress on relapses should open new fields for fundamental investigations on the pathophysiological process responsible for ISSNS and on neuroendocrine-immunological interactions.

## **Study objective**

Research question 1:

Is the occurrence of relapses related to an increased level of perceived stress?

Research question 2:

Is the occurrence of relapses related to individual and/or familial reactions to stressful life events?

Research question 3:

Is the occurrence of relapses related to individual and/or familial reactions to stressful life events?

Research question 4:

Can salivary secretion patterns of cortisol and amylase be correlated with the occurrence of relapses in stressful situations?

## **Study design**

1-12-2012 Inclusion;

1-12-2013 End of inclusion;

1-12-2014 End of follow-up.

## **Intervention**

Computer based questionnaires.

## Contacts

### **Public**

AMC, Emma Children's Hospital  
L. Zoetebier  
Amsterdam  
The Netherlands

### **Scientific**

AMC, Emma Children's Hospital  
L. Zoetebier  
Amsterdam  
The Netherlands

## Eligibility criteria

### **Inclusion criteria**

1. Children from 5 to 12 years of age at the time of inclusion;
2. Patient is classified as steroid sensitive;
3. Patient known to present with at least one relapse / year or patients with a first presentation of the idiopathic nephrotic syndrome. Relapse definition: dipstick protein '++' on 3 consecutive days.

### **Exclusion criteria**

1. Non idiopathic nephrotic syndrome;
2. No remission after 4 weeks prednison 60 mg/m<sup>2</sup>/day;
3. Children younger than 5 or older than 12 years.

## Study design

## Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

## Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-12-2012
Enrollment:	40
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	31-01-2013
Application type:	First submission

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
NTR-new	NL3647

**Register**

NTR-old

CCMO

ISRCTN

**ID**

NTR3829

NL41194.018.12

ISRCTN wordt niet meer aangevraagd.

## Study results

**Summary results**

N/A