Antihistamines in the treatment of ADHD and allergy.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24270

Source
Nationaal Trial Register

Health condition

attention-deficit/hyperactivity
disorder (ADHD), atopy, allergy, eczema, asthma, allergic rhinitis

Sponsors and support

Primary sponsor: Dr. T.W. de Vries
Medical Center Leeuwarden
Pediatrics
P.O. BOX 888
8901 BR Leeuwarden
Tel. 058-2863385
Fax. 058-2863390
e-mail: tjalling.de.vries@znb.nl
Source(s) of monetary or material Support: Dr. T.W. de Vries
Medical Center Leeuwarden
Pediatrics
P.O. BOX 888
8901 BR Leeuwarden
Tel. 058-2863385
Fax. 058-2863390
e-mail: tjalling.de.vries@znb.nl

Intervention

Outcome measures

Primary outcome

Decrease of 5 points on the SNAP-IV as rated by the parent(s).

Symptoms of asthma, eczema and rhinitis, which will be scored using the Asthma Control Questionnaire (ACQ), a validated tool to assess asthma control among children in clinical trials, the validated Three Item Skin Score (TISS) questionnaire, which is a practical and useful tool for the intended eczema assessment, and the Total 4 Symptom Score (T4SS).

Secondary outcome

- Amount of sleep and sleeping problems, measured by a questionnaire on sleeping problems.

- The score of ADHD in categories hyperactivity, inattention and impulsivity, as rated by the parents, measured by the SNAP IV Parent rating scale.

- The score of ADHD total and in categories hyperactivity, inattention and impulsivity, as rated by the teacher, measured by the SNAP IV Teacher rating scale.

- Frequency of adverse events of alimemazine and methylphenidate, measured by a questionnaire on adverse events.

Study description

Background summary

The prevalence of attention-deficit/hyperactivity disorder (ADHD) has increased enormously over the last decade. Recent studies showed a significant association between ADHD and atopic diseases such as asthma, rhinitis, and eczema. Recently, we confirmed the association in the General Practitioner Research Database, a large British database in which prescription data of boys who were prescribed ADHD medication were compared with matched controls. We found a significant increase of risk for having an atopic disease in patients with ADHD. One explanation for the association could be that histamine and histamine-receptors play a role in both ADHD and allergic diseases. For allergic diseases it has been established that histamine plays a key role in allergic reactions; in fact, systemic antihistamines are used as first line drugs to treat allergic symptoms such as those of allergic rhinitis. Histamine-

receptors are present in every organ system and histamine is an important neurotransmitter.

Pelsser and coworkers treated boys with ADHD with a diet low of allergens and found a significant decrease in ADHD-symptoms. We hypothesize that the use of systemic antihistamines will decrease ADHD symptoms as well as allergic symptoms in children with ADHD who are treated with methylphenidate and who have comorbid asthma and/or allergic rhinitis and/or eczema. For this trial we will use alimemazine, a registered systemic antihistaminic drug that has been used for long times in many children in and outside the Netherlands, and which has an acceptable safety profile.

We hypothesized that adding alimemazine to existing ADHD treatment will decrease ADHD-symptoms as reported by parents and school teachers as well as allergic symptoms.

Study objective

We hypothesized that adding alimemazine to existing ADHD treatment will decrease ADHD-symptoms as reported by parents and school teachers as well as allergic symptoms.

Study design

At inclusion, 4 weeks after start of treatment and 4 weeks after crossover.

Intervention

The study is designed as a randomized cross-over study. Participants aged 6-12 years are using methylphenidate and will be asked to continue their treatment as prescribed by their physician throughout the study. The intervention consists of the extra use of a tablet of 5 mg alimemazine, a H1-receptorantagonist or a placebo (vitamin B) complex as add-on therapy over one month, followed by use of the alternative compound over a month, in a 1:1 ratio randomly in either order.

Contacts

Public
Rijksuniversiteit Groningen
J. Schans, van der
Groningen
The Netherlands
Scientific
Rijksuniversiteit Groningen
J. Schans, van der
Groningen
The Netherlands

Eligibility criteria

Inclusion criteria

The study will include children in whom the diagnosis of ADHD has established by a professional and who use methylphenidate and who have comorbid atopic diseases as atopic eczema, asthma, or allergic rhinitis.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Being diagnosed with any chronic disease other than ADHD, including diabetes and epilepsy.

- Being treated with other medications on a daily base. Interval treatment with painkillers, bronchodilators, ointments, drops etc. are allowed.

- Unable to fulfill study procedures

- Not fluent in Dutch language

- Sufficiently treated and no improvement expected, as judged by the parents.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	06-01-2015
Enrollment:	70
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL4749
NTR-old	NTR4877
Other	Medisch Centrum Leeuwarden : 8925

Study results