Antihistamines in the treatment of ADHD and allergy.

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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.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24270

Bron
Nationaal Trial Register

Aandoening

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

Ondersteuning

Primaire sponsor: Dr. T.W. de Vries
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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Rijksuniversiteit Groningen
J. Schans, van der
Groningen
The Netherlands

Wetenschappelijk

Rijksuniversiteit Groningen
J. Schans, van der
Groningen
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	06-01-2015
Aantal proefpersonen:	70

Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4749
NTR-old	NTR4877
Ander register	Medisch Centrum Leeuwarden : 8925

Resultaten