Systemic antihistamines in the treatment of attention-deficit/hyperactivity disorder (ADHD): a pilot study.

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Primary objectiveTo assess whether the use of alimemazine improves symptoms of allergic diseases and ADHD, as scored by the parents using standardized questionnaires (Sample Snap IV rating scales)

Ethical review	Not approved
Status	Will not start
Health condition type	Allergic conditions
Study type	Interventional

Summary

ID

NL-OMON42065

Source
ToetsingOnline

Brief title
Antihistamines in the treatment of ADHD.

Condition

- Allergic conditions
- Cognitive and attention disorders and disturbances

Synonym
ADHD, attention deficit and hyperactivity disorder; allergy

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: Wetenschapsfonds Medische Staf MCL

Intervention

Keyword: ADHD, alimemazine, allergic diseases, Antihistamines

Outcome measures

Primary outcome

Primary determinant is the score of symptoms of the allergic disease and of ADHD, measured by the SNAP IV Teacher and Parent rating scale, as filled in by parents

Secondary outcome

The score of ADHD symptoms, as rated by the school teachers using the SNAP IV Teacher and Parent rating scale. Frequency of side effects of alimemazine and methylphenidate, measured by a questionnaire on side effects, amount of sleep and sleeping problems.

Study description

Background summary

Attention-deficit/hyperactivity disorder (ADHD) is a common neurobehavioral disorder which emerges before the age of 7 years. Epidemiological studies showed that ADHD has an estimated prevalence rate of 5% among school-aged children, with a 3 to 4-fold higher rate for boys than girls. [1] ADHD is characterized by behavioral symptoms like inattention, impulsivity, hyperactivity and social disabilities. The diagnostic and statistical manual for mental disorders (DSM IV) is the standard used for ADHD diagnosis; it is based particularly on these characteristics of ADHD. For what is known at this moment, ADHD does not have one overall cause, it is more likely that various factors influence the occurrence of the disorder. Factors such as environment, nutrition and genetics have been mentioned in former research based on their association with ADHD.
Like ADHD, atopic diseases are also very common among children. In the Netherlands approximately 115,000 children are diagnosed with asthma and it has been indicated that about 20% of the children has a type of atopic disease in general. In many children these diseases co-occur. As an example, children with

asthma have a higher chance on development of atopic rhinitis, and the other way around, than children without atopic diseases. As ADHD and atopic diseases are both most common diseases among children, this finding raised the question whether there is a common causal pathway. Research data on this subject show conflicting results, but all mention a possible raise of risk. Recently, we confirmed the association in the General Practitioner Research Database a large British database and found an increased risk for atopic diseases in boys with ADHD. [4]
The possibility that both allergic diseases and ADHD have a common pathophysiology has been posed before. Pelsser et al discussed this and studied the influence of a diet, low in allergens, in children with ADH. She found a significant and relevant decrease of ADHD symptoms. The diet, however, was difficult to keep. [6]
Another way to influence a possible common pathophysiology could be to use antihistamines. Histamine plays a key role in the development of allergic symptoms by blocking histamine-receptor. To date, at least three types of histamine-receptors have been identified. Type I is important in allergy, type II is necessary in the production of gastric acid and type III is recognized as a cerebral transmitter. As far as we know, there is only one study started to a pharmacological intervention of allergy and ADHD, results of this study are not published. Other studies on this subject are low in quality, due to low number of participants or design, such as blinding.

Study objective

Primary objective

To assess whether the use of alimemazine improves symptoms of allergic diseases and ADHD, as scored by the parents using standardized questionnaires (Sample Snap IV rating scales)

Study design

This is a cross-over study. After inclusion the patients will use the alimemazine/placebo for 4 weeks and then the symptoms will be assessed. After one week for wash-out, the patients will use placebo/alimemazine for 4 weeks and then the symptoms will be assessed again.

Intervention

The intervention will be the use of 5 mg alimemazine, an antihistaminic drug, once daily for 4 weeks.

Study burden and risks

ADHD is a relatively common disorder, affecting 5% of school chidren. At this

moment, methylphenidate is the drug of choice. We will study whether the addition of alimemazine will influence ADHD symptoms. In an earlier study we found that in the group of children with ADHD more children have an allergic disease and this could mean that there is a common pathway in pathofysiology.

We consider the burden of using one tablet of 5 mg alimemazine once daily relatively low. These children use tablets of methylphenidate for a prolonged period. The risk of alimemazine is drowsiness and sleepiness. Therefore we will advice the children to take the medication for bed-time. so that this side effect is minimalised.
If we find that adding alimemazine is beneficial for these children with a mimimun of side-effects, this will give another treatment option for this group. Some children have side effects during the use methylphenidate and therefore do not use more despite the fact sometimes they still have symptoms. When we find that alimemazine is beneficial we can diminish the symptoms without increasing side effects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

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 phase:	4
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	60

Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Alimemazine
Generic name:	alimemazine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Vitamin B complex
Generic name:	Vitamin B complex
Registration:	Yes - NL outside intended use

Ethics review

Not approved

Date:	26-03-2015
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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
EudraCT	EUCTR2014-002793-36-NL

Register	ID
CCMO	NL48392.000.15
Other	NTR 20863