The Inca study: Impact of Nutrition on Children with ADHD. A randomised, controlled trial into the effects of a few foods diet on the behaviour of a heterogeneous, not selected group of primary school children, meeting the DSM-IV-criteria of ADHD

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1. Randomised controlled determination of the influence of foods on the behaviour of a heterogeneous not-selected group primary school children, during the first two months of the trial. 2. Determination of an IgG or IgE-mediated respons to foods,...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Allergic conditions
Study type	Interventional

Summary

ID

NL-OMON30659

Source
ToetsingOnline

Brief title
INCA study

Condition

- Allergic conditions
- Psychiatric and behavioural symptoms NEC

Synonym

HKS (Hyperkinetic Syndrome), hyperactivity

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: pro health, deel van het bloedonderzoek is in kind,Stichting Kinderpostzegels Nederland;Stichting Nuts-Ohra;Stichting Kind en Gedrag

Intervention

Keyword: ADHD, children, diet, immunology

Outcome measures

Primary outcome

Parent and teacher ratings on the Short Conners List and the ADHD Rating Scale,

with three important measure points: At the start of the trial, after a

baselineperiod, and at the end of the diet or waiting list period.

Secondary outcome

The levels of IgE and IgG before and after the diet, comorbid problems like ODD

and physical complaints, comparing the controlgroup with the dietgroup and each

child with itself.

Study description

Background summary

ADHD is a higly hereditable disorder, our knowledge of the mechanism leading to ADHD are speculative however, thus restricting the prospects of prevention. Some environmental influences may play a role in the manifestation of the disorder. One of these factors may be nutrition. Previous research into the influence of foods on ADHD showed convincing double-blind controlled evidence, but further research was advised to define the target subgroup, these studies mostly concerning selected groups of children. Therefore the subjects in this study will be an aselect, group, not selected on affinity with dietary

interventions. The hypothesis is tested that the results of previous research are also applicable to a heterogeneous group of children suffering from ADHD. It might be conceivable that immunological mechanisms, by means of IgG- or IgE-antibodies, play a role in children with ADHD being sensible to foods. To examine this possibility, bloodtests will be done before and after following an elimination diet, to determain the IgE levels and the IgG-levels of at least 250 different foods. The hypothesis will be tested that, in children showing a significant decrease in symptoms after following the elimination diet, foods with low IgG-levels are not a causal factor of ADHD. Finally the hypothesis is tested that 75% of the subjects are capable to keep to a diet.

Study objective

1. Randomised controlled determination of the influence of foods on the behaviour of a heterogeneous not-selected group primary school children, during the first two months of the trial. 2. Determination of an IgG or IgE-mediated respons to foods, to investigate whether bloodtests in children with ADHD may contribute to dietary intervention, in the third month of the trial. 3. Investigation of the long-term effect of a diet on ADHD, during month 4-12 of the trial.

Study design

100 children, the ADHD diagnosis being confirmed by a paediatrician, will be randomly assigned to either a diet group or a control group. The trial can be divided in two phases, in the first phase the efficacy of an elimination diet will be investigated, in the second phase will be determined which foods are involved. During the first phase, after a baselineperiod for the dietgroup as well as the controlgroup, the dietgroup will follow an elimination diet, whilst the control group will be placed on a waiting list and adhere to their normal food pattern. Only children showing significant improvement in behaviour (responders) will enter the second phase, the provocation phase. The first phase and the first 4 weeks of the second phase is a randomised controlled trial (week 1-13), being followed by an open trial (week 14-52). Blood tests will be executed at the start of the trial (week 0), after the diet phase (week 9) and at the end of the RCT (week 13). The four most important measure points are in week 0, 9, 13, 52.

Intervention

Children have to stick to an elimination diet for 5 weeks, the responders (improvement of behaviour of at least 40%) going on with an individually assessed provocation diet, based on the IgG-bloodtests in week 0. The control group is placed on a waiting list, but are offered to start with the elimination diet after the last RCT measure point (week 13).

Study burden and risks

The most important burden is the adherence to a different diet than the children are used to. Previous studies showed that this, according to the parents, is not a big problem. The diet has to be followed for only five weeks, which is not too long. After the diet children are allowed to eat everything again (nonresponders), or the diet will be expanded (responders) The obtaining of the blood samples may be a burden to the children, but a present to be choosed will probably solve this problem. The children will be investigated by a paediatrician once. There are no extra risks involved associated with participation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Diagnosis ADHD,according to the DSM-IV, combined or hyperactive/impulsive subtype.
Age 4-8.
No medication to improve the behaviour, e.g. methylphenidate, is prescribed.
The behaviour problems started before reaching the age of four.
Willing to go through bloodtests three times.

Exclusion criteria

Family conditions, impeding the compliance to the diet.
The child has had or has lately been following an elimination diet.
The child is already engaged in a therapeutic treatment for the behaviour problems.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2008
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission

Review commission: METC Wageningen Universiteit (Wageningen)

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
CCMO	NL12736.081.06