Effecten van een hoge eiwitinname bij kinderen met obesitas.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24325

Source
Nationaal Trial Register

Brief title
High protein intake and obesity

Health condition

obesity, metabolic syndrome, insulin sensitivity

Sponsors and support

Primary sponsor: Sophia Children's Hospital - Erasmus MC Rotterdam
Source(s) of monetary or material Support: Sophia B.V.

Intervention

Outcome measures

Primary outcome

The change in body composition (body fat%, fat-free mass, fat mass, fat-free mass index, fat mass index , waist and hip circumference, waist:hip ratio) in obese children who consumed a high protein diet for 4 weeks. Measurements will be performed with a DEXA-scan and the deuterium dilution technique.

Secondary outcome

Whole body protein turnover, gluconeogenesis, energy expenditure, insulin sensitivity, and markers of dyslipidemia and oxidative stress, measured with stable isotoop techniques.

Study description

Background summary

Rationale:

The increasing prevalence of childhood obesity is a major health problem. In obese adults, high protein diets have shown to increase weight loss and preserve fat-free body mass. The effectiveness of these diets can be attributed to favourable effects on both sides of the energy balance, i.e. high protein diets suppress appetite and thereby reduce energy intake and they increase energy expenditure. It is not clear whether these beneficial effects are also present in children. The exact mechanism via which a high protein diet increases energy expenditure is not known, but may be related to increased protein and amino acid metabolism.

Objective:

To assess the effects of a 4-week high protein diet on body composition in obese children. Secondary outcomes are whole-body protein turnover, gluconeogenesis, energy expenditure, markers of the metabolic syndrome, appetite sensations, concentrations of (an)orexigenic hormones, and fMRI responses to visually presented food stimuli.

Study design:

The study has a randomized, crossover, double blind design with 2 intervention periods of 4 weeks separated by a wash-out period of 2 weeks. On day 0 and 28 of both intervention periods the children come to the university hospital for a series of measurements.

Study population:

Obese, pre-pubertal children (age 8-12 years) with a Body Mass Index standard deviation score (BMI-SDS) > 2.3 who are on the waiting list of the ‘Dikke Vrienden Club’ (DVC), a cognitive behavioral therapy program for obese children. Exclusion criteria are obesity that is

caused by a somatic treatable disorder and use of systemic steroids.
Intervention: Consumption of a high protein diet (HP) or a normal protein diet (NP).

Main study parameters/endpoints:

The change in body composition (body fat%, fat-free mass, fat mass, fat-free mass index, fat mass index , waist and hip circumference, waist:hip ratio) in obese children who consumed a high protein diet for 4 weeks. Secondary endpoints are whole body protein turnover, gluconeogenesis, energy expenditure, insulin sensitivity, and markers of dyslipidemia and oxidative stress.

Study objective

In obese children who consume a relatively high protein diet for 4 weeks, the combination of reduced energy intake resulting from an increased satiety and increased energy expenditure together with sparing of fat-free mass induces weight loss which results in a 'healthier' body composition, i.e. a lower body fat% and a higher fat-free mass index.

Study design

Measurements at day 0 and day 28 of both intervention periods (4 'testdays'). Some additional measurements outside testdays, like a questionnaire concerning appetite and a food diary.

Intervention

Consumption of a high protein diet (HP) or a normal protein diet (NP). The children will consume 2 supplements per day. The study has a randomized, crossover, double blind design with 2 intervention periods of 4 weeks separated by a wash-out period of 2 weeks.

HP: Protein, NP: Carbohydrates & fat, protein-free.

The high protein diet strives to dubble the proteinintake to a energy percentage of 25. The children will be given a proteinpowder two times a day which is processed in a milkshake, a pancake or yoghurt. One is taken just before breakfast and one just before dinner. The control group receives also 2 supplements a day, consisting of an iso-energetic control powder with carbs and fat but no protein. This powder is also given through a milkshake, pancake or yoghurt.

Contacts

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Eligibility criteria

Inclusion criteria

1. Boys & girls;

2. Obesity (BMI-SDS>2.3);

3. Age 8-12 years;

4. Pre-pubertal (Tanner stage 1);

5. On waiting list of 'Dikke Vrienden Club'.

Exclusion criteria

1. Obesity that is caused by a somatic treatable disorder;

2. Use of systemic steroids.

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):	01-07-2010
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-06-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39425
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2252

Register	ID
NTR-old	NTR2372
CCMO	NL30264.078.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39425

Study results

Summary results
N/A