

Effects of high protein intake in obese children

Published: 31-05-2010

Last updated: 19-03-2025

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,...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON39425

Source

ToetsingOnline

Brief title

High protein intake and obesity

Condition

- Other condition
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym

obesity, overweight

Health condition

obesitas en daaraan gerelateerde aandoeningen

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: onderzoeksbeurzen;nog geen exacte bekend,onderzoeksbeurzen vanuit bedrijfsleven en/of societies;nog geen exacte bekend

Intervention

Keyword: body composition, children, dietary proteins, obesity

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.

Secondary outcome

Whole body protein turnover, gluconeogenesis, energy expenditure, insulin sensitivity, cortisol concentration in hair, and markers of dyslipidemia and oxidative stress . The endpoints whole body protein turnover, gluconeogenesis, synthesis rate of apolipoprotein B100 and the synthesis rate of glutathione will be measured in a subgroup of the children, as there will be no more intravenous infusion of stable isotopes from March 2014 onwards.

Study description

Background summary

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 less 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.

Study 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 responses to visually presented food stimuli. The concentration of cortisol in hair is determined to study a possible relationship between cortisol, stress and obesity and the metabolic syndrome.

Study design

The study has a randomized, crossover, single 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. The study will be conducted in 2 study centers: the Sophia Children's Hospital-Erasmus MC and the VU university medical center Amsterdam.

Intervention

Consumption of a high protein diet (HP) or a normal protein diet (NP). In HP, children's (ad libitum) habitual diets will be supplemented with ~13% of energy from protein per day in order to double daily protein intake. The children will consume 2 supplements per day (milkshake, dessert, or pancake; the children are free to choose what they prefer most): 1 in the morning (before breakfast) and 1 in the evening (before dinner). When the children are on the NP diet they will receive two isoenergetic control supplements containing carbohydrates and fat but no protein.

Study burden and risks

Children that participate in the study will consume 2 milkshakes per day for a period of 8 weeks in total. They will keep a diary and visit the hospital 4 times for a series of measurements that will take about 7 hours in total per day. The amount of blood samples is minimal using a venous catheter. From March 2014 onwards, there will be no more intravenous infusion of stable isotopes. The length of the hospital visit will be reduced to approximately 3 hours per day. The children may benefit from participation in the study by an improvement in body composition and possible other improvements in for instance markers of the metabolic syndrome. The risks with participation are negligible. The study specifically focuses on effects of dietary proteins in obese children as more

clinical and scientific knowledge is needed in this population.

Contacts

Public

Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 60
Rotterdam 3015 GJ
NL

Scientific

Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 60
Rotterdam 3015 GJ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

- obesity (BMI-SDS > 2.0)
- age 8-12 years
- pre-pubertal (Tanner stage 1)
- child and parents/caretakers are highly motivated to participate in the study
- written informed consent of the parents/caretakers

Exclusion criteria

- obesity that is caused by a somatic treatable disorder
- use of systemic steroids

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	24-05-2011
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO	
Date:	31-05-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	23-06-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	19-04-2012

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-02-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-12-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 24325
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL30264.078.10
OMON	NL-OMON24325