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Adipocytokine levels in obese children before and after lifestyle intervention

Submission date
28/08/2015

Recruitment status
No longer recruiting

Registration date
10/09/2015

Overall study status
Completed

Last Edited
03/09/2015

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Childhood obesity is a serious health risk worldwide. Studies have shown that obesity in childhood can lead to serious conditions in adulthood, such as diabetes and heart disease. Beyond this, being overweight as a child can seriously affect physical and emotional development, and therefore effective treatments are urgently needed. Fat (adipose tissue) produces a number of chemicals known as adipocytokines such as leptin and adiponectin, which are important for controlling metabolism. Leptin works by telling the brain that the body has enough fat stored. Because the more fat there is, the more leptin is produced; people with obesity have very high levels of leptin, which leads to the body becoming resistant to its effects, causing a person to eat more and use less energy, increasing the risks of obesity-related diseases. Adiponectin on the other hand is anti-inflammatory, and can actually help prevent these diseases. It has been found that in people who are obese, levels of adiponectin are lower than normal, which increases the risk of diabetes and heart disease. Adipose tissue also releases chemicals that co-ordinate inflammation, such as c-reactive protein (CRP), which can lead to increased risk of obesity-related diseases when raised. It is thought that eating more healthily and exercising more can help to re-regulate these chemicals. The aim of this study is to find out whether a program which motivating children to exercise and eat healthily can help weight loss and cause changes to the levels of adiponectin, leptin and CRP.

Who can participate?
Overweight or obese children, with a BMI of more than 22.

What does the study involve?
Children and their families are invited to take part in a lifestyle intervention lasting for one year. Within the year, they attend seven outpatient appointments in the pediatric department. These appointments include physical examinations, guidance for having a more healthy diet and motivational behavioral therapy, encouraging children to change their habits in order to lose weight. The children also take part in an exercise program twice a week, including one hour of physical activity. Weight changes are monitored throughout the study, and the children have blood tests at the start and end of the study to measure their levels of adiponectin, leptin and CRP. One year after the study ends, children and their families are invited to a follow up examination with a nurse.

What are the possible benefits and risks of participating?
Benefits of participating include weight loss and a lower risk of heart disease, stroke and obesity. There are no real risks of participating, apart from discomfort during the collection of blood samples.

Where is the study run from?
Department of Pediatrics, Regional Hospital Viborg (Denmark)

When is the study starting and how long is it expected to run for?
January 2010 to January 2012

Who is funding the study?
1. Department of Pediatrics, Regional Hospital Viborg (Denmark)
2. Council of Sport, Municipality of Viborg (Denmark)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Investigations of levels of adiponectin, leptin, and CRP in a cohort of 11-13-years old children before and after a lifestyle intervention program.

Study objectives
Our study investigates the effect of a multidisciplinary family-based intervention program on the level of weight reduction, focusing on changes in diet, structural physical activity and motivational behavior therapy among obese 11-13 years old, obese Danish children. The investigation included an assessment of the association between measurements of obesity and levels of adipocytokines and CRP.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Danish National Committee on Biomedical Research Ethics, 25/01/2012, ref: 1-10-72-567-12
2. Danish Data Protection Agency, 27/06/2011, ref: 2007-58-0010.

Study design
Interventional multidisciplinary study.

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
This material is only available in Danish

Health condition(s) or problem(s) studied
Obesity

Interventions
The children and their families are followed at the out-patient clinic at the Pediatric Department at 7 consultations during one year. Three visits are individual and included physical examination by pediatrician. Six visits included motivational behavioral therapy individually (2 visits) or in small groups (4 visits) leaded by child psychologist, pediatrician and pediatric nurse.
The exercise program is organized by two health workers and performed two times a week, including 60 minutes of physical exercise. The children and their families receive three individual nutritional guidance sessions by a clinical dietitian in addition to six cooking arrangements during the intervention program.
One year after the intervention ended the children and their families are re-invited to a follow-up examination conducted by a pediatric nurse in the out-patients clinic.

Intervention Type

Behavioural

Primary outcome measure
1. The degree of weight loss and weight changes. Weight, height and BMI was registrated every third month during the intervention period.
2. Changes in adiponectin, leptin and c-reactive protein (CRP) are measured before and after the intervention. Adiponectin (mg/l) is determined by a validated in-house time-resolved immunofluorometric assay based on two monoclonal antibodies and recombinant human adiponectin (obtained from R&D Systems, Abingdon, UK). Leptin (µg/l) is determined by a validated in-house time-resolved immunofluorometric assay based on commercial available monoclonal antibodies and recombinant human leptin (R&D Systems, Abingdon, UK). CRP levels are determined by a high sensitive CRP (hsCRP) TRIFMA assay based on commercial available monoclonal antibodies (R&D systems).

Secondary outcome measures
1. Waist circumference, measured every third month during the intervention.
2. Hip circumference, measured every third month during the intervention.
3. Blood pressure, measured every third month during the intervention.

Overall study start date
01/09/2009

Completion date
01/01/2012

Eligibility

Key inclusion criteria
1. Aged between 11-13 years
2. BMI ≥ 22 (this value at the age of 12 years old correlates to BMI of 25 in an adult)

Participant type(s)
Patient

Age group
Child

Lower age limit
11 Years

Upper age limit
13 Years

Sex
Both

Target number of participants
30

Key exclusion criteria

Considerable comorbidity which would make participation in structural physical activity impossible.

Date of first enrolment
01/09/2009

Date of final enrolment
01/01/2010

Locations

Countries of recruitment
Denmark

Study participating centre
Pediatric Department
Regionshospitalet Viborg (Regional hospital Viborg)
Heibergs Alle 4
Viborg
Denmark
8800

Sponsor information

Organisation
Regional Hospital Viborg

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/008cz4337

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Department of Pediatrics, Regional Hospital Viborg

Funder Name
Council of Sport, Municipality of Viborg

Results and Publications

Publication and dissemination plan
An article will be submitted to the journal Acta Paediatrica, where the study design and results will be described.

Intention to publish date
31/12/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available