

The pro- and anti inflammatory marker study: Children and adolescents with overweight or obesity.

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The first objective of our study to explore the relation between pro- and anti- inflammatory markers (hsCRP, TNF- α , IL-1 β , IL-6, IL-8, leptin, adiponectin) and BMI z-score in obese children participating in our intervention programs (AanTafel!, de...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON36961

Source

ToetsingOnline

Brief title

The pro- and anti inflammatory marker study. The PAIM- Study.

Condition

- Other condition
- Lifestyle issues

Synonym

inflammation, obesity

Health condition

obesitas en overgewicht en mate van inflammatie

Research involving

Human

Sponsors and support

Primary sponsor: Ziekenhuisvoorzieningen Gelderse Vallei

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: child, inflammation, obesity, treatment

Outcome measures

Primary outcome

The primary study outcome is BMI z-score in relation to pro- and anti-inflammatory markers

Secondary outcome

- Body composition: Mid Upper Arm Circumference (MUAC), Waist Circumference (WC), skin folds
- Cardiovascular risk factors: blood pressure, glucose tolerance, insulin resistance, triglycerides, High Density Lipoprotein (HDL) and Low Density Lipoprotein (LDL) cholesterol
- Health Related Quality of Life
- Dietarian intake, eating behaviour, physical activity and sedentary behaviour
- > Change in lifestyle

Study description

Background summary

The prevalence of childhood obesity and overweight is increasing dramatically, becoming one of the most alarming public health issues. Obesity is associated with significant health problems in the pediatric age. Cardiovascular risk factors (hypertension, dyslipidemia, and type 2 diabetes) are increasingly recognized in obese children. It is associated with increased risk of

cardiovascular mortality and morbidity in adulthood.

Visceral adipose tissue and its adipose tissue resident macrophages produce many proinflammatory cytokines like Tumor Necrosis Factor- α (TNF- α), Interleukin-6 (IL-6), less adiponectin and interleukin-10 (IL-10). Circulating inflammatory markers (TNF- α , high sensitivity C- reactive protein (hsCRP), IL-6) and hemostatic markers (fibrinogen, von Willebrand Factor (vWF), D-dimer, Thrombin-Antithrombin complex (TAT)) are higher in obese children in comparison with non-obese children. Adiponectin levels are decreased and leptin levels increased in obese children. Few studies have addressed the effects of long-term multidisciplinary intervention on pro- and anti-inflammatory cytokine levels. More and more evidence suggest that low-grade inflammation predicts an increased risk of chronic disease and promotes its progression. The association between diet, physical activity and obesity is well established, and between obesity and inflammation. There may, however, also be indirect associations between dietary compounds, patterns of physical activity and fitness with inflammation. Because of the severe consequences of childhood overweight and obesity treatment is necessary. In hospital Gelderse Vallei children with obesity are treated by means of a multidisciplinary program. The treatment programs are Aan Tafel! (children aged 3 to 8 years), de Dikke Vrienden Club (children 8 to 12 years), SLIM2 (adolescents aged 12-18 years). The reduction of visceral fat/substantial weight loss in obese adolescents (interdisciplinary lifestyle therapy) showed a decreased pro-inflammatory and an increased anti-inflammatory state. According to the literature about 30% of the patients participating in a multidisciplinary programs will have a substantial weight loss resulting in an improvement of cardiovascular risk factors. About 40-60% of the patients have no substantial weight loss and about 4-15% of the patients have a deterioration in BMI-SDS score. Our hypothesis is that we expect that patients without substantial weight loss with an improved lifestyle will show a lower grade of inflammation than patients without substantial weight loss not improving their lifestyle. In addition we expect patients with a substantial weight loss will show a decrease in inflammation while an increase in weight will show higher grade of inflammation.

Study objective

The first objective of our study to explore the relation between pro- and anti-inflammatory markers (hsCRP, TNF- α , IL-1 β , IL-6, IL-8, leptin, adiponectin) and BMI z-score in obese children participating in our intervention programs (AanTafel!, de Dikke Vrienden Club and SLIM2) followed by the maintenance program in an observational setting. The second objective is to ascertain if a healthier lifestyle (adequate caloric intake according to age and gender and more physical activity) causes a decline in pro- inflammatory markers and an increase in anti-inflammatory markers in children without substantial weight loss after 1 year of treatment.

Study design

Longitudinal observational study

Study burden and risks

The burden and risks associated with participation to this study are minimal. Before the start of the treatment program, at the end of the intensive part and at the end of the program HRQoL, eating behaviour, coping style (only adolescents) and pro- and anti-inflammatory markers will be measured. The HRQoL, eating behaviour, and coping style will be both assessed by a questionnaire. Completing both questionnaires will take 40-60 minutes. No additional vena puncture is required. Blood samples for research purposes will be taken at the same time as the blood samples taken for standard care. Usually no extra hospital visits are needed for this study. There will be no benefit for the individual participating in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Children (2-11 years)

Inclusion criteria

- Participation in AanTafel!, de Dikke Vrienden Club, SLIM2 (intervention program for children and adolescents in the age of 3 to 8 years; 8-12 year and 12-19 year respectively) with overweight or obesity in Ziekenhuis Gelderse Vallei followed by the maintenance program
- Informed consent from patients (12 years and older) and parents or guardian

Exclusion criteria

No exclusion criteria

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 24-04-2013

Enrollment: 163

Type: Actual

Ethics review

Approved WMO

Date: 15-02-2013

Application type: First submission

Review commission: METC Wageningen Universiteit (Wageningen)

Approved WMO	
Date:	26-09-2013
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO	
Date:	27-05-2016
Application type:	Amendment
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	NL41253.081.12