# 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- $\alpha$ , IL-1 $\beta$ , 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

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# **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 sudy outcome is BMI z-score in relation to pro- and anti-

inflammatoiry 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- $\alpha$  (TNF- $\alpha$ ), Interleukin-6 (IL-6), less adiponectine and interleukin-10 (IL-10). Circulating inflammatory markers (TNF- $\alpha$ , 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. Adiponectine 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 physicial 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 multidisciplinairy 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 multidisciplinairy 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 detorioration 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 shower higher grade of inflammation.

## Study objective

The first objective of our study to explore the relation between pro- and antiinflammatory markers (hsCRP, TNF- $\alpha$ , IL-1 $\beta$ , 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

## 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 punction 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

#### Public

Ziekenhuisvoorzieningen Gelderse Vallei

Willy Brandtlaan 10 Ede 6716 RP NL **Scientific** Ziekenhuisvoorzieningen Gelderse Vallei

Willy Brandtlaan 10 Ede 6716 RP NL

# **Trial sites**

# **Listed location countries**

Netherlands

# **Eligibility criteria**

**Age** Adolescents (12-15 years)

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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) |

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| 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 CCMO ID NL41253.081.12