

The effect of a three-days-during calories restrictive diet on unhealthy abdominal deposited fat; A study in patients who are planned for elective cholecystectomy.

Published: 19-08-2010

Last updated: 03-05-2024

Objective: To study differences of (adipo) cytokine spectra in visceral and peripheral adipose tissue and to study the effect of caloric restriction on (adipo) cytokine production of these different fat tissues.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON34973

Source

ToetsingOnline

Brief title

Caloric restriction on (adipo) cytokine production of fat.

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Appetite and general nutritional disorders

Synonym

too much wrong fat, visceral obesity

Research involving

Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep

Source(s) of monetary or material Support: Wetenschappelijke Activiteiten Commissie
Reinier de Graaf Groep

Intervention

Keyword: (adipo) cytokine, caloric restriction, culture, fat

Outcome measures

Primary outcome

Main study parameters/endpoints: The effect of caloric restriction on (adipo) cytokine production.

Secondary outcome

Differences of (adipo) cytokine spectra of visceral and peripheral adipose tissue

Study description

Background summary

Rationale: Obesity is a risk for cardiovascular disease and mortality. One of the mechanisms is inflammatory (adipo) cytokine production by visceral fat tissue. (Adipo) cytokines enhance the inflammatory response in the arterial wall and contribute to atherosclerotic disease.

Study objective

Objective: To study differences of (adipo) cytokine spectra in visceral and peripheral adipose tissue and to study the effect of caloric restriction on (adipo) cytokine production of these different fat tissues.

Study design

Study design: A randomised controlled single (investigator) blinded trial.

Intervention

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Intervention (if applicable): Two groups, each 25 patients will be formed, one group of patients being treated with 600 Kcal kCal restriction for 3 days prior to surgery and one group treated with 2000 Kcal prior to surgery.

Study burden and risks

Sampling of a small specimen of peripheral and visceral fat tissue prolongs the surgery time with a few minutes. 600 Kcal restriction prior to the surgery could be experienced as cumbersome.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

1. Obese patients (BMI >27 Kg/m²)
2. Anyone planned for gallbladder surgery.
3. Informed consent signed by patient
4. Male and female patients aged 18 * 60 years

Exclusion criteria

1. Unwillingness to cooperate with the study procedures
2. History of an active malignancy
3. BMI <27 Kg/m²
4. ESR >20
5. Serum albumin <30 g/l at entry of the study
6. Treatment with hypolipidemic drugs
7. Treatment with anti- inflammatory drugs (including glucocorticosteroids, Non-steroidal anti-inflammatory drugs)
8. Diabetes (fasting blood glucose >7.1 mmol/l)
9. Use of anti-diabetic agents
10. No written informed consent
11. pregnancy

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Basic science

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	23-12-2010
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date: 19-08-2010

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

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	NL31786.098.10