

IMAGE trial: Intestinal Microbiota & Adipose Gene Expression.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21738

Source

NTR

Brief title

IMAGE trial

Health condition

gut microbiota, obesity, fat adipose tissue

Sponsors and support

Primary sponsor: Academic Medical Center,Amsterdam

Source(s) of monetary or material Support: Academic Medical Center, Amsterdam

Intervention

Outcome measures

Primary outcome

Expression of genes in adipose tissue will be compared to gut microbiota composition.

Secondary outcome

We will try to relate regulation of genes to plasma markers of inflammation.

Study description

Background summary

Objective: To investigate correlations between gene expression in adipocytes and gut microbiota composition in relation to plasma markers of inflammation.

Study design: Cross-sectional design.

Study Population: Healthy men and women scheduled for elective laparoscopic cholecystectomy.

Outcome measures: Expression of human genes will be first tested on Affimetrix microarrays and genes of interest will thereafter be assessed by quantitative real-time RT-PCR. These genes in adipose tissue will be compared to gut microbiota composition. Finally we will try to relate regulation of genes to plasma markers of inflammation.

Sample Size: It is estimated that a total of 200 patients (100 males and 100 females) are needed.

Study objective

We hypothesize that genetically programmed developmental differences in adipocytes are under direct regulation of fecal flora composition which thus plays an important role in obesity, body fat distribution and systemic inflammation.

Study design

Cross-sectional design, only 1 timepoint.

Intervention

During the planned surgery visceral and subcutaneous biopsies will be obtained. In all patients venous blood samples will be taken and the patients will collect a feces sample.

Contacts

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Eligibility criteria

Inclusion criteria

1. Healthy men and women, scheduled for elective laparoscopic cholecystectomy;
2. Age 18-85 yrs;
3. BMI 18-45 kg/m².

Exclusion criteria

1. Generalized inflammation;
2. Antibiotic use last three months;
3. Malignant disease;
4. Metformin use.

Study design

Design

Study type: Observational non invasive

Intervention model:	Parallel
Allocation:	Non controlled trial
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-06-2010
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion	
Date:	25-05-2010
Application type:	First submission

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
NTR-new	NL2211
NTR-old	NTR2335
Other	CCMO : 29210
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A