Metabolic phenotyping of individuals with abdominal obesity and high levels of hepatic fat before and after dietary interventions

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON40205

Source
ToetsingOnline

Brief title
Belly Fat Study

Condition

- Other condition

Synonym
abdominal fat, Fatty liver

Health condition

algehele gezondheid, metabole gezondheid

Research involving

Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Belly Fat, Liver, Metabolic flexibility, Phenotyping

Outcome measures

Primary outcome

Lipid accumulation in the liver (MRS)

Body fat distribution (MRI)

Physical fitness (VO2 max in a maximal exercise test)

After a challenge meal:

Metabolic plasma markers (cardio-metabolic risk factors, gut function, adipose tissue and muscle health)

Peripheral blood mononuclear cells (gene expression patterns)

Satiety and well-being (questionnaires)

Adipose tissue en muscle biopsies (genome/epigenome determinations)

Vascular functions (vascular health, blood pressure, aterial stiffness)

Secondary outcome

Brain activity (fMRI)

Olfactory test

Questionnaire on food preferences

Study description

Background summary

It is known that in particular visceral fat (abdominal obesity) and fat deposition in non-adipose tissue such as the liver are important factors related to metabolic health, such as the degree of insulin resistance, dyslipidaemia and other well-established cardio-metabolic risk factors.

The arise of pathological consequences of abdominal obesity are a result of a disturbance in the elegant interplay between metabolic organs, such as the liver, adipose tissue, muscle and gut. These organs interact with each other via signaling molecules and metabolites. An imbalance in the secretion of these substances may lead to impaired functioning and health of these organs.

Determination of the health of these organs can be accomplished by, in particular, by subjecting these organs to a challenge meal (for instance a high fat or sugar load) to measure how the body and the specific organs are able to cope with this stressor. By examining these organs in a more dynamic state, one can gain more insight in the metabolic flexibility of these organs.

Lifestyle, in particular dietary habits, plays an important role in abdominal obesity and the health of metabolic organs, especially the liver. Several nutrients have demonstrated to exert positive or negative effects on the health and functioning of metabolic organs. A diet (whole dietary approach) can thus be a power tool to improve the health status of individuals with abdominal obesity by improving organ health.

Study objective

The objective of the Belly Fat project is to accurately determine the personal health status of individuals with higher levels of abdominal fat (belly fat) and hepatic fat. This so-called phenotyping is essential to allow intervening with dietary and life style changes before the onset of disease.

The primary objective of this study is to compare the effects of two different diets on the static metabolic health status as assessed by determination of organ health and, more specifically, of lipid accumulation in the liver. The application of a mixed meal challenge test will be used to gain insight in the dynamic metabolic health status.

A secondary objective is to determine the reaction (brain activity) of individuals with abdominal obesity after visual and olfactory food-cues.

Study design

The Belly Fat Study is an intervention study in which subjects with high levels of abdominal fat and a higher intrahepatic lipid (IHL) accumulation are extensively phenotyped before and after receiving dietary advice which is deployed as a tool to induce weight loss and to improve organ health.

Intervention

Allocation to one of the two designed dietary advices, counselling by professional dieticians.
Both diets are based on a caloric restriction of 30%.

(1) Dietary advice based on a more Western dietary pattern: 30E% fats (saturated and unsaturated), 15E% protein (animal and vegetable sources), 50-55E% carbohydrates (complex carbohydrates and simple carbohydrates e.g. the monosaccharide fructose).
(2) Dietary advice based on a combination of nutrients of which we expect (based on scientific literature) that it will cause a larger improvement in organ health and reduction in liver fat when compared to the standard diet: 30-35E% fats (mono- and poly unsaturated fatty acids, ~1400mg n-3 fatty acids), 20-25E% protein (mainly vegetable sources, mainly soy) and 40-45% carbohydrates (low glycaemic index, complex carbohydrates, low in fructose).

Furthermore, a control group is added in which participants do not receive any form of intervention.

Study burden and risks

- Subjects that will participate in the study will invest a total of 23-27 hours.
- The dietary advice is prepared by qualified dieticians, hence it does not pose the participants at any risk for deficiencies or excessive consumption of certain nutrients.
- Participants in the control group are offered dietary counselling (including a recipe book) and the end of the study periode, hence they will also profit frorm health benifits.
- (f)MRI/MRS is a non-invasive and safe procedure as long as no contraindication is met (metal devices such as aneurysm clips, neural stimulators, pacemakers/defibrillators, cochlear implant etc.).
- The physical fitness test may cause some physical discomfort, such as muscle aches, irregular heartbeat, cramping or an abnormal blood pressure. To minimize these risks, subjects will be monitored throughout the whole test in terms of heart rate, blood pressure and O2 consumption. The test will be discontinued in case abnormalities are detected.
- The Hb value of each participants will be determined before participation, individuals cannot participate in the study if this value is below 8.4 mml/L. Blood collection will therefore not lead to anaemia.

- Adipose tissue and muscle biopsies can occasionally cause a local hematoma or bruise and some participants may report pain or discomfort.
- Fructose will be supplied to participants in the standard group in the form of normal food products such as fruit juice, hence the risk of habituation is minimal.

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

Age 40-70y at the time of recruitment
BMI >27kg/m2 or waist circumference >102cm (males) or >88cm (females)

Exclusion criteria

Hb levels <8.4 mmol/L
Diabetic (normoglycemic according to WHO criteria (OGTT, fasting blood glucose< 7 mmol/L, after 2 hr <11.1 mmol/L)
Daily intake of alcohol of >30g (men) or >20g (women)
Tobacco smoker
Abuse of drugs
Any medical conditions or (metal) devices interfering with or posing a risk for the participant in 1H-MRS/MRI scanning (e.g. claustrophobia, pace maker, surgical screws/pins, artificial joints or heart valves, etc.)
Diagnosed with any long-term medical condition (i.e. cardiovascular disease, gastrointestinal disease, renal dysfunction)
Use of medications known to interfere with glucose or lipid homeostasis (i.e. corticosteroids)
Allergic to fish oil or unwilling to consume fish oil supplements
Unwilling to comply with dietary guidelines
Restricted to a vegetarian dietary regime

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-10-2014
Enrollment:	110
Type:	Actual

Ethics review

Approved WMO

Date:	03-06-2014
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	08-08-2014
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	NL44614.081.13