Adipose tissue oxygen tension: adipose tissue depot differences and functional consequences

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The results of this research will elucidate the differences in oxygen tension and further effects for both adipose tissue depots in obese, insulin resistant woman. A recent study showed an increased oxygen tension in obese insulin resistant subjects...

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

Summary

ID

NL-OMON40421

Source
ToetsingOnline

Brief title
Adipose tissue depot differences in oxygen tension

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
adult-onset diabetes, type 2 diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: European Foundation for the Study of Diabetes

Intervention

Keyword: Blood flow, Hypoxia, Obesity, Type 2 diabetes

Outcome measures

Primary outcome

Differences in oxygen tension and further effects for both adipose tissue depots in obese, insulin resistant woman will be investigated. We will perform our experiments in the abdominal and femoral adipose tissue depots and also monitor the blood flow in both depots. Next to this we will also determine the local inflammation.

The primary parameter is:

- oxygen tension in adipose tissue

Secondary outcome

Secundary parameters are:

- adipose tissue blood flow
- insulin sensitivity
- inflammation markers in adipose tissue (IL-6, TNF-alfa, CD68, leptin, adiponectin, MCP-1, MIF1, PPAR-gamma, CD34 mRNA expressie)
- bodyweight, body mass index (BMI) and body composition
- whole body adipose tissue distribution (DEXA scan)
- adipocyte size
- plasma glucose concentration
- plasma insulin concentration
- glucose tolerance

- FFA, triacylglycerol, glycerol concentrations

- bloodpressure

We will also isolate cells from the biopsies and expose them to different concentrations oxygen. With this experiment we will investigate the effects of oxygen tension on adipocyte metabolism and inflammation.

Study description

Background summary

Research showed that adipose tissue is active as an organ and plays an important role in the metabolism. Individuals with obesity and type 2 diabetes have a disturbed adipose tissue. Convincing evidence showed that this disturbance is important in the development of insulin resistance (reduced effect of the hormone insulin) and type 2 diabetes.
Recently, we have shown that subjects with overweight/obesity and insulin resistance have an increased oxygen tension. There are two major adipose tissue depots: abdominal and femoral (upper leg). According to literature these depots have different characteristics, and the femoral depot is suggested to have a more beneficial effect. We expect the oxygen tension to play a part in this difference and that through our study we can characterize both depots.

Study objective

The results of this research will elucidate the differences in oxygen tension and further effects for both adipose tissue depots in obese, insulin resistant woman. A recent study showed an increased oxygen tension in obese insulin resistant subjects.
This research will contribute to an increased insights in the existence and development of insulin resistance and type 2 diabetes. This could lead to improved prevention and treatment of insulin resistance, type 2 diabetes and/or related diseases.

Study design

Candidate-subjects will be selected through a screening, which will show if an individual is suitable for this research. Screening will be performed with more individuals than the actual study population. The results obtained from the

screening will be used to evaluate if an individual is suitable for this research. Participation in the screening will not necessarily result in participation in the research.
If an individual is suitable for this research they will have to visit the university 3 times (see "tijdsinvestering" page 7 of the "proefpersooninformatie", dutch only) for measurements leading to answers on our research questions.

Intervention

n/a

Study burden and risks

All measurements are easy to cope with, without additional related risks. The insertion of the canule can incidentally cause a hemorrhage. The biopsies will be taken under local anesthesia by an experienced individual. A hemorrhage can occur at the place of the biopsy and this area can stay sensitive for several days. The biopsies will leave a small scar (approximately 3 mm).

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

- Woman with overweight/obesity (body mass index >= 28 kg/m2) and a disturbed glucose metabolism (IFG: 6.1-7.0 mmol/l (or 5.6-7.0 mmol/l and a family history of diabetes) and/or IGT: 2h plasma glucose during OGTT 7.8-11.1 mmol/l)
- postmenopausal
- Age: 40-65
- Non smoking
- A stable bodyweight for at least 3 months (no change in bodyweight: < 3kg)

Exclusion criteria

- diabetes mellitus
- cardiovascular diseases
- cancer
- asthma or bronchitis
- liver and/or kidney disease (determined based on ALAT and creatinine levels, respectively)
- a disease with a life expectancy < 5 years (will be questioned for each individual)
- alcohol and/or drug abuse (alcohol consumption > 15 units/week)
- plans to lose weight (subjects will be asked if they have weight loss plans (e.g. to increase their physical activity level or change diet): a positive answer will lead to exclusion)
- participation in sport activities for more than 3 hours/week
- Usage of higher doses anti-oxidants (vitamin A, C, E, beta-carteen; standard multi-vitamin supplements are allowed when the concentrations are less than: 800ug/day Vit A, 60mg/day Vit C, 10mg/day Vit E and 400ug/day beta-caroteen)
- use of medication with an effect on the glucose metabolism or inflammation
- not able to understand the subject information
- smoking

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2014
Enrollment:	14
Type:	Actual

Ethics review

Approved WMO

Date:	27-01-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	14-04-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL46328.068.13