

# GM3 and insulin sensitivity.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON21599

### Source

Nationaal Trial Register

### Brief title

GM3

### Health condition

Diabetes, obesity, insulin resistance,

## Sponsors and support

**Primary sponsor:** Academic Medical Center (AMC), Department of Endocrinology and Metabolism

**Source(s) of monetary or material Support:** Academic Medical Center (AMC), Department of Endocrinology and Metabolism

## Intervention

## Outcome measures

### Primary outcome

- Peripheral glucose uptake (Rd)
- Gangliosides concentration in muscle and adipose tissue

### Secondary outcome

- Plasma concentration of glucoregulatory hormones
- Energy expenditure
- Carbohydrate oxidation and fat oxidation
- VO2 max
- Muscle fiber type

## Study description

### Background summary

Gangliosides reside within the plasma membrane and are able to modulate insulin signaling at the level of the insulin receptor. The most abundant ganglioside is GM3. Recently, we and others have shown in rats that pharmacologically reducing GM2 and GM3 levels results in amelioration of high fat diet induced insulin resistance. In this study we want to explore if gangliosides are elevated in muscle and adipose tissue of obese subjects insulin resistant subjects compared to matched healthy controls.

### Study objective

We hypothesize that membrane-residing gangliosides are elevated in obese insulin resistant subjects and correlate to peripheral insulin resistance.

Furthermore, we hypothesize that the perturbation of the insulin signaling cascade by elevated gangliosides is caused by a reduced phosphorylation of the insulin receptor.

### Study design

N/A

### Intervention

None:

This is a comparative study; 10 obese men matched for gender and age with 10 lean men.

## Contacts

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## Eligibility criteria

### Inclusion criteria

Inclusion criteria for all participants

1. Written informed consent
2. Caucasian
3. Able to keep a normal day and night rhythm during the study period (i.e. no shift work)
4. Stable weight for at least 3 months
5. Age 20-55 years

Inclusion criteria for healthy volunteers:

1. 20 ≤ BMI ≤ 25 kg/m<sup>2</sup>
2. Fasting glucose level of < 5.6 mmol/L, in addition to a glucose level of < 7.8 mmol/L at 2 hours after intake of 75 g glucose (OGTT).

Inclusion criteria for obese subjects:

1. BMI >30 kg/m<sup>2</sup>
2. Fasting glucose level of < 7 mmol/L, in addition to a glucose level of < 11.0 mmol/L at 2 hours after intake of 75 g glucose (OGTT).
3. HOMA IR > 2.7

## Exclusion criteria

Exclusion criteria for all participants:

1. Participation in an investigational drug trial within 90 days prior to our study
2. history of or current abuse of drugs or alcohol (>14 U/week)
3. Smoking
4. Vigorous physical activity
5. Family history of DM II
6. Familial dyslipidemia
7. Any medical condition except hypertension and dyslipidemia in the obese group
8. Use of any medication except for anti-hypertensives, excluding ACE-inhibitors/All-antagonists.

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Pending

Start date (anticipated):	10-12-2008
Enrollment:	20
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	18-11-2008
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	NL1471
NTR-old	NTR1540
Other	: MEC 08/280
ISRCTN	ISRCTN wordt niet meer aangevraagd

## Study results

### Summary results

N/A