

Are the blood plasma adipokine and inflammatory marker concentrations different between obese and non-obese type 2 diabetes patients?

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| Submission date 04/06/2009 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 24/07/2009 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 24/07/2009 | Condition category Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

1

Study information

Scientific Title

Plasma adipokine and inflammatory marker concentrations in obese and non-obese type 2 diabetes patients: an observational cross-sectional study

Acronym

LIRO

Study objectives

We hypothesise that altered plasma adipokine, inflammatory factor, and/or free fatty acid (FFA) levels are related to the obese state only and, as such, are not prevalent in non-obese type 2 diabetes patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Local medical ethical committee of the Virga Jesse Hospital, Hasselt, Belgium approved on the 25th November 2004 (ref: 04.37/cardio04.041)

Study design

Observational cross-sectional study

Primary study design

Observational

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Type 2 diabetes

Interventions

Overall, groups were matched for age and habitual physical activity (estimated by questionnaire). Additionally, non-obese type 2 diabetes patients and normoglycemic controls were matched for body mass index. Non-obese and obese type 2 diabetes patients were matched for basal fasting glucose concentrations. Fasting blood samples were collected to compare glycosylated hemoglobin (HbA1c) content, blood lipid profile, insulin, adiponectin, resistin, leptin, interleukin-6, high-sensitivity C-reactive protein, tumour necrosis factor alpha, and free fatty acid concentrations between groups. Moreover, Homeostatic Model Assessment (HOMA) index, fat free mass and whole-body oxygen uptake and workload capacity were compared between groups. All measurements were undertaken at similar time during the day (between 8.00 and 12.00 AM).

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Fasting blood samples are collected to compare the following between groups:

1. Adiponectin
2. Resistin
3. Leptin
4. Interleukin-6
5. High-sensitivity C-reactive protein
6. Tumour necrosis factor alpha
7. Free fatty acid concentrations

Subjects arrived at the hospital by car or public transportation and reported at the laboratory at 08.00 AM after an overnight fast. After 20 minutes of rest a venous blood sample was collected.

Key secondary outcome(s)

Fasting blood samples are collected to compare the following between groups:

1. Glycosylated haemoglobin (HbA1c) content
2. Blood lipid profile
3. Insulin level
4. Homeostatic Model Assessment (HOMA) index
5. Fat-free mass
6. Whole-body oxygen uptake
7. Workload capacity

Subjects arrived at the hospital by car or public transportation and reported at the laboratory at 08.00 AM after an overnight fast. After 20 minutes of rest a venous blood sample was collected.

Completion date

01/01/2009

Eligibility

Key inclusion criteria

A total of 60 Caucasian males (aged between 40 and 75 years) are selected to participate in this study: 20 non-obese (body mass index [BMI] less than 30 kg/m²) and 20 obese (BMI greater than 35 kg/m²) type 2 diabetes patients, and 20 healthy, non-obese subjects (BMI less than 30 kg/m²). Type 2 diabetes patients are diagnosed for at least 12 months prior to investigation and are all treated with oral blood glucose lowering medication. All subjects are sedentary and do not participate in any regular exercise program and/or caloric intake restriction intervention for at least 5 years.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

Key exclusion criteria

1. Type 1 diabetes patients
2. Females
3. Non-adult patients
4. Deregulated diabetes

Date of first enrolment

01/01/2008

Date of final enrolment

01/01/2009

Locations

Countries of recruitment

Belgium

Netherlands

Study participating centre

Department of Human Movement Sciences

Maastricht

Netherlands

6200 MD

Sponsor information

Organisation

University Maastricht (UM) (Netherlands)

ROR

<https://ror.org/02jz4aj89>

Funder(s)

Funder type

Research organisation

Funder Name

Hartcentrum Hasselt vzw (Netherlands)

Funder Name

University Maastricht (UM) (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration