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

Submission date 04/06/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 24/07/2009	**Overall study status** Completed	
Last Edited 24/07/2009	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cross-section survey

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/01/2008

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/m^2) and 20 obese (BMI greater than 35 kg/m^2) type 2 diabetes patients, and 20 healthy, non-obese subjects (BMI less than 30 kg/m^2). 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

Age group
Adult

Sex
Male

Target number of participants
60

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
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Sponsor information

Organisation
University Maastricht (UM) (Netherlands)

Sponsor details
Postbus 616
Maastricht
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Sponsor type
University/education

Website
http://www.unimaas.nl

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration