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Effects of hypocaloric diets at different glucose load on endothelial function and glycaemic variability in adult obese subjects with increased cardiovascular risk

Submission date 26/11/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/12/2010	**Overall study status** Completed	
Last Edited 09/01/2014	**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

03/2009

Study information

Scientific Title
Effects of hypocaloric diets at different glucose load on endothelial function and glycaemic variability in adult obese subjects with increased cardiovascular risk: a longitudinal, open-label, randomised controlled trial

Study objectives
Different glycaemic index/glucose load nutritional aproaches to obesity, as well as weight loss per se, may have a different impact on endothelial function and on glycaemic homeostasis, two factors influencing both cardiovascular and diabetes risk.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Investigator Revisory Board of the University of Palermo approved on 12th February 2009 (ref. ORPA07R2ZF)

Study design
Longitudinal open label randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Cardiovascular and metabolic diseases; clinical nutrition

Interventions
Participants will be randomly assigned respectively to a hypocaloric low or high glucose-load diet. Both diet will have similar macronutrient composition. After three months of dieting participants will follow a similar body weight maintainance dietary treatment for 9 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Endothelial function, measured as "flow mediated dilation"
2. Glycaemic variability, measured by the subcutaneous continuous glucose monitoring method

These measurements will be obtained three times, respectively before (0 months), after hypocaloric diet (3 months) and body weight maintenance periods (12 months).

Secondary outcome measures
1. Traditional anthropometric, metabolic and cardiovascular risk factors
2. Intra-renal haemodynamic measurements (resistance and pulsatility indexes)
3. Carotid intima-media thickness

These measurements will be obtained three times, respectively before (0 months), after hypocaloric diet (3 months) and body weight maintenance periods (12 months).

Overall study start date
01/11/2010

Completion date
01/01/2012

Eligibility

Key inclusion criteria
1. Male and female subjects
2. Range of age 18 - 60 years
3. Range of body mass index (BMI) 28 - 39.9 kg/m^2
4. Presence of at least one of the diagnostic criteria of the metabolic syndrome:
4.1. Waist circumference greater than 80 cm for women and 94 cm for men
4.2. Triglycerides greater than 150 mg/dl or use of lowering blood lipid drugs
4.3. High density lipoproteins (HDL)-cholesterol less than 50 mg/dl for women or 40 mg/dl for men
4.4. Blood pressure greater than 130 mmHg for systolic or greater than 85 mmHg for diastolic blood pressure
4.5. Fasting plasma glucose greater than 100 mg/dl

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80 subjects; the primary outcome "glycaemic variability" will be measured in only 30% of participants (about 24 subjects)

Key exclusion criteria
1. Type 1 or 2 diabetes
2. Gastro-intestinal, connective diseases
3. Chronic pancreatitis, liver cirrhosis, kidney stones, renal failure
4. Use of acetyl-salicylic acid (ASA), other antiplatelet drugs, statins, oral hypoglycemic drugs, nitrates, non-steroidal anti-inflammatory drugs (NSAIDS), corticosteroids, drugs interfering with coagulation, supplements with vitamins and anti-oxidants
5. Pregnancy or lactation in the last six months
6. Regular sport activity
7. Denial of informed consent

Date of first enrolment
01/11/2010

Date of final enrolment
01/01/2012

Locations

Countries of recruitment
Italy

Study participating centre
Department of Internal Medicine, Cardiovascular and Kidney Diseases
Palermo
Italy
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Sponsor information

Organisation
University of Palermo (Italy)

Sponsor details
Department of Internal Medicine, Cardiovascular and Kidney Diseases
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Sponsor type
University/education

Website
http://portale.unipa.it/

ROR
https://ror.org/044k9ta02

Funder(s)

Funder type
Government

Funder Name
Ministry of Education and Research (Ministero dell'Università e della Ricerca [MURST]) (Italy)

Alternative Name(s)
Министерство образования и науки, Ministry of Education and Research, HM

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Estonia

Funder Name
Onlus: Nutrition and Health (Associazione Onlus: Nutrizione e Salute) (Italy)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2013		Yes	No