

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

<b>Submission date</b> 26/11/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 16/12/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 09/01/2014	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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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 approaches 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 maintenance 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<sup>2</sup>
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

90127

**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?
<a href="#">Results article</a>	results	01/06/2013		Yes	No