

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	<input type="checkbox"/> Prospectively registered
Registration date 16/12/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 09/01/2014	Condition category 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
Prof Silvio Buscemi

Contact details
Department of Internal Medicine, Cardiovascular and Kidney Diseases
Via del Vespro, 129
Palermo
Italy
90127
silbus@tin.it

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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).

Key secondary outcome(s)

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).

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/m²
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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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

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