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Effects of Sicilian red oranges on endothelial function and plasma antioxidant activity in adult subjects with increased cardiovascular risk

Submission date 07/02/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/02/2010	**Overall study status** Completed	
Last Edited 19/06/2012	**Condition category** Circulatory System	

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
1/2010

Study information

Scientific Title
Effects of Sicilian red oranges on endothelial function and plasma antioxidant activity in adult subjects with increased cardiovascular risk: a randomised placebo-controlled trial

Study objectives
Red oranges contain antioxidants that may improve endothelial function and plasma antioxidant capacity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethical Committee of the University Hospital of Palermo (I) approved on the 3rd February 2010 (ref: 02/2010)

Study design
Randomised 2 x 2 crossed placebo-controlled single blinded trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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
Cardiovascular and metabolic diseases

Interventions
Participants with increased cardiovascular risk will receive on two periods of 7 +/- 1 days (period 1 and 2) each with 3 days intervals, with a random order respectively 500 ml/day (250 ml twice daily [bid]) of red orange juice and 500 ml of placebo made up of orange aroma and colorant, water, 11 g of saccarose, 1 g of citric acid.

Intervention Type
Other

Phase

Not Applicable

Primary outcome measure
Endothelial function, measured as "flow mediated dilation", blood total oxidant and anti-oxidant capacity before period 1 and at the end of period 1 and 2.

Secondary outcome measures
1. Glycaemic profiles and variability, before period 1 and at the end of period 1 and 2
2. Different measures of leukocytes activation and of nitric oxide production, before period 1 and at the end of period 1 and 2

Overall study start date
01/03/2010

Completion date
31/05/2010

Eligibility

Key inclusion criteria
1. Male and female subjects
2. Range of age 18 - 70 years
3. Body mass index (BMI) greater than 28 kg/m^2
4. Presence of at least two 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
14 - 20 subjects + 10 controls

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
01/03/2010

Date of final enrolment
31/05/2010

Locations

Countries of recruitment
Italy

Study participating centre
Dipartimento di Medicina Interna, Malattie Cardiovascolari e Nefrourologiche
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
Agrumaria Corleone s.p.a. Palermo (Italy) - provided red orange juice and placebo

Funder Name
Added 23/02/2010:

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	01/05/2012		Yes	No