

Short and middle term comparison of the effects of hypocaloric low carbohydrate diet versus Mediterranean diet on endothelial function measured by means of flow mediated dilation

Submission date
02/04/2007

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
13/04/2007

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
21/04/2009

Condition category
Nutritional, Metabolic, Endocrine

☐ 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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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

01/2007

Study information

Scientific Title

Study objectives

Different nutritional approaches to obesity might influence a different endothelial function.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the local Ethical Committee of the University of the Studies of Palermo on the 6th June 2007 (ref: 7/07). Ethics approval was not necessary before the first patient was recruited for several reasons:

1. The enrolled subjects are obese people that spontaneously ask a dietetic treatment for losing weight
2. No drugs are administered
3. Two safe hypocaloric diets that are traditionally employed in the clinical field are compared (the low carbohydrate diet and the Mediterranean diet)
4. Participants are asked for a written informed consent before participation
5. The study is performed according to the Helsinki declaration
6. There is no conflict of interest and the study has no external sponsor to the University (Italian Ministry of University and Scientific and Technological Research)
7. No invasive measurements are performed

Study design

Longitudinal, randomised, open study.

Primary study design

Interventional

Secondary study design

Single-centre

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Obesity

Interventions

Group one: hypocaloric low carbohydrate diet for two months

Group two: hypocaloric Mediterranean diet for two months

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Short (five to seven days) and middle (two months) modifications of flow mediated dilation.

These will be measured three times:

1. Before starting the diet treatment
2. Five to seven days after starting the diet treatment
3. Two months after starting the diet treatment

Secondary outcome measures

1. Traditional anthropometric, metabolic and cardiovascular risk factors
2. Intra-renal haemodynamic measurements (resistance and pulsatility indexes)

These will be measured three times:

1. Before starting the diet treatment
2. Five to seven days after starting the diet treatment
3. Two months after starting the diet treatment

Overall study start date

01/10/2006

Completion date

30/04/2007

Eligibility

Key inclusion criteria

1. Female subjects
2. Range of age 30 to 50 years
3. Range of Body Mass Index (BMI) from 27 kg/m² to 39.9 kg/m²
4. Non-diabetic, non-hypertensive, non-dislipidemic subjects

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

Key exclusion criteria

1. Any metabolic, cardiovascular or systemic disease
2. Any drug treatment

Date of first enrolment

01/10/2006

Date of final enrolment

30/04/2007

Locations**Countries of recruitment**

Italy

Study participating centre

Dipartimento di Medicina Interna, malattie cardiovascolari e nefrourologiche

Palermo

Italy

90127

Sponsor information**Organisation**

University of Palermo (Italy)

Sponsor details

Piazza Marina

Palermo

Italy

90100

Sponsor type

University/education

Website

<http://www.unipa.it/>

ROR

<https://ror.org/044k9ta02>

Funder(s)

Funder type

Government

Funder Name

Italian Ministry of the University of Scientific and Technological Research (Ministero Dell'università E Della Ricerca Scientifica E Tectnologica [MURST]) (Italy) - 60% funds

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 | 01/05/2009 | | Yes | No |