

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

Prof Silvio Buscemi

Contact details

Dipartimento di Medicina Interna, malattie cardiovascolari e nefrourologiche

Via del vespro, 129

Palermo

Italy

90127

Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Longitudinal, randomised, open study.

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

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

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