

# 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

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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

### **Study design**

Longitudinal, randomised, open study.

### **Primary study design**

Interventional

### **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/m<sup>2</sup> to 39.9 kg/m<sup>2</sup>
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?
<a href="#">Results article</a>	results	01/05/2009		Yes	No