

# Effect of dietary glycaemic load on body weight, inflammation and endothelial function

**Submission date**  
10/06/2010

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
15/07/2010

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
26/03/2020

**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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Spain  
43201

## Additional identifiers

**Protocol serial number**  
PV10046S

## Study information

**Scientific Title**  
Effect of dietary glycaemic load on body weight, inflammation and endothelial function: a randomised controlled trial

**Acronym**  
GLYNDIET

**Study objectives**

The acute or chronic intake of low-glycaemic foods will create loss of body weight and will generate a metabolic response associated with an improvement in systemic inflammatory pattern and markers of endothelial function compared to the consumption of high-glycaemic index carbohydrates or consumption of a low-fat diet.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Institutional Review Board of the Hospital Universitario Sant Joan de Reus, Spain, 26/02/2009

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Obesity

**Interventions**

Participants are randomised into three groups stratified by sex, and presence of diabetes using random triplets:

1. Diet rich in low-glycaemic index carbohydrates (40% of energy from fat, 42% of energy from low-glycaemic index carbohydrates, 18% of energy from proteins)
2. Diet rich in high-glycaemic index carbohydrates (40% of energy from fat, 42% of energy from high-glycaemic index carbohydrates, 18% of energy from proteins)
3. Low-fat diet (30% of energy from, 52% of energy from high-glycaemic index carbohydrates, 18% of energy from proteins)

Total duration of treatment and follow-up is six months.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Weight loss, measured at baseline, after 15 days, and every month until end of study

**Key secondary outcome(s)**

1. Adiposity measures, measured at baseline and end of study
2. Blood sugar and insulin, measured at baseline and end of study
3. Lipid profile, measured at baseline and end of study
4. Markers of inflammation, measured at baseline and end of study

5. Markers of endothelial function, measured at baseline and end of study
6. Adipose tissue expression of inflammatory markers, measured at baseline and end of study
7. Inflammatory post-prandial response, measured at first visit
8. Satiety, measured at baseline, after 15 days, and every month until end of study

**Completion date**

31/12/2012

## Eligibility

**Key inclusion criteria**

1. Men and women aged between 30 - 60 years
2. Body mass index (BMI) between 27 and 35 kg/m<sup>2</sup>

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Total final enrolment**

122

**Key exclusion criteria**

1. Non controlled type 2 diabetes mellitus (HbA1c greater than 8%)
2. Systolic blood pressure (SBP) greater than 159 mmHg and diastolic blood pressure (DBP) greater than 99 mmHg
3. Low density lipoprotein (LDL) cholesterol higher than 160 mg/dl
4. Triacylglycerol (TAG) higher than 400 mg/dl
5. Secondary overweight
6. Any inflammatory disease, infectious, chronic obstructive pulmonary, neoplastic, endocrine or haematological disease active at the time of the study
7. Leukocyte count greater than or equal to 11,000 cells x 10<sup>6</sup>
8. Taking of anti-inflammatory drug therapy, steroids, hormones or antibiotics that could affect the parameters analysed in the study
9. Changes in medication for lipid profile, diabetes or hypertension in the past three months previous to the study
10. Active alcoholism or drug dependence, excluding tobacco
11. Highly restrictive diet for 3 months before the study or latest weight loss (more than 5 kg in the last 3 months)
12. Medical condition that discourages the inclusion in the study
13. The inability to understand it or the anticipated difficulty in making dietary changes according to the model of Prochaska and DiClemente

**Date of first enrolment**

03/02/2010

**Date of final enrolment**

31/12/2012

## Locations

**Countries of recruitment**

Spain

**Study participating centre**

Institut d'Investigacions Sanitàries Pere i Virgili

Reus

Spain

43201

## Sponsor information

**Organisation**

Pere Virgili Health Research Institute (Institut d'Investigació Sanitària Pere Virgili) (Spain)

**ROR**

<https://ror.org/01av3a615>

## Funder(s)

**Funder type**

Research organisation

**Funder Name**

Pere Virgili Health Research Institute (Institut d'Investigació Sanitària Pere Virgili) (Spain)

## 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               | 01/07/2014   |            | Yes            | No              |
| <a href="#">Results article</a> | results               | 01/01/2018   |            | Yes            | No              |
| <a href="#">Results article</a> | results               | 01/01/2019   | 15/05/2019 | Yes            | No              |
| <a href="#">Results article</a> | results               | 01/04/2018   | 02/09/2019 | Yes            | No              |
| <a href="#">Results article</a> | miRNA profile results | 01/02/2019   | 26/03/2020 | Yes            | No              |
| <a href="#">Study website</a>   | Study website         | 11/11/2025   | 11/11/2025 | No             | Yes             |