

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

Submission date 10/06/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 15/07/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/03/2020	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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/m²

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 10⁶
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?
Results article	results	01/07/2014		Yes	No
Results article	results	01/01/2018		Yes	No
Results article	results	01/01/2019	15/05/2019	Yes	No
Results article	results	01/04/2018	02/09/2019	Yes	No
Results article	miRNA profile results	01/02/2019	26/03/2020	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes