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

Submission date	Recruitment status	[_] Prospectively registered
10/06/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/07/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/03/2020	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.glyndiet.org/

Contact information

Type(s)
Scientific

Contact name
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43201

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
03/02/2010

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^2

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
n = 117

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 10^6
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)

Sponsor details

Sant Llorenc 21
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Spain
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Sponsor type
Research organisation

Website
http://www.iispv.cat/

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

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	01/07/2014		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