

Relationship between a low fructose consumption and insulin resistance

Submission date 04/11/2016	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 15/11/2016	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 06/05/2020	Condition category Nutritional, Metabolic, Endocrine	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Insulin resistance (IR) is a condition in which the cells of the body do not respond normally to the hormone insulin, leading to high blood sugar levels. IR is a strong predictor for the development of type 2 diabetes mellitus and cardiovascular disease (heart and blood vessel disease). Fructose (a natural sugar found in plants) has become a widely-used additive in many food industry products such as soft drinks and nonalcoholic beverages, generally in the form of fructose-enriched corn syrup. The aim of this study is to determine whether a low fructose diet supervised by a physician or nurse decreases IR compared to a standard diet.

Who can participate?

Overweight and obese adults aged between 29 and 66.

What does the study involve?

Health care zones are randomly allocated to one of two groups. Those in the first group are asked to follow a low fructose diet. Those in the second group are advised to eat a standard diet. The calories in diets in both groups contain around 30-40% less than each individual's calorie requirements to help them to lose weight. Participants in both groups provide blood samples at the start of the study and then again after 24 and 48 weeks to assess insulin resistance. In addition, the cholesterol and fat levels in the blood and their BMI are measured at the same timepoints.

What are the possible benefits and risks of participating?

There are no direct benefits involved with participating. There is a small risk of pain, bruising or bleeding when blood samples are taken.

Where is the study run from?

Primary care centers in the island of Tenerife (Canary Islands, Spain)

When is the study starting and how long is it expected to run for?

May 2012 to December 2017

Who is funding the study?

1. Instituto de Salud Carlos III (Spain)
2. Fundacion Caja Canarias (Spain)

Who is the main contact?

Dr Santiago Domínguez-Coello

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Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

ISCI 012/00231 and OBE04/2013

Study information

Scientific Title

Effect of a diet low in fructose and sucrose on insulin resistance: clinical trial in primary care

Acronym

DISFRUTE

Study objectives

A low fructose/sucrose diet reduces insulin resistance more than a standard diet.

Ethics approval required

Old ethics approval format

Ethics approval(s)

CEIC Hospital Universitario Nuestra Señora de Candelaria-Tenerife-Canary Islands Spain, 23/05/2012, ref: 160

Study design

Single-blind multi-centre randomised controlled trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Insulin resistance

Interventions

Participants are randomized by health care zone to one of two groups.

Low-fructose diet intervention (LFDI) group: Participants are assigned to health centers in the western zone of Tenerife island. They are advised to eat a low-fructose diet (1000, 1250, 1500, 1750, 2000, 2250, 2500 or 2750 kcal/day). Low-fructose diets are designed by calculating free and total (free + fructose associated with sucrose) fructose contents in standard diets. Foods with a fructose content in the highest quartile for the amounts corresponding to the standard diet are removed from the standard diet.

Standard diet control (SDC) group: Participants are assigned to health centers in the eastern zone of the island. They are advised to eat a standard diet (recommended by the Canary Health Service).

The kcal/day in the prescribed diets are calculated as 30% or 40% less than the kcal/day in the participant's energy requirements for his or her ideal weight according to age, sex and physical activity.

Follow up for all participants takes place at 4, 8, 12, 20, 24 and 48 weeks, and involves nutrition counseling and reinforcement, as well as the measure of weight, waist circumference and blood pressure.

Intervention Type

Other

Primary outcome(s)

Insulin resistance is estimated from fasting serum glucose (measured with enzymatic methods) and insulin concentrations (measured with a chemiluminescence immunoassay method) with a computer-based Homeostasis Model Assessment system (HOMA2-IR) at baseline, 24 and 48 weeks.

Key secondary outcome(s)

1. Body mass index is determined using weight and height measurements at baseline, 4, 8, 12, 20, 24 and 48 weeks
2. Waist circumference is determined using a nonstretchable measuring tape at baseline, 4, 8, 12, 20, 24 and 48 weeks
3. Total Cholesterol, HDL cholesterol and triglycerides are measured using enzymatic methods at baseline, 24 and 48 weeks. LDL cholesterol is calculated using the Friedewald formula

Completion date

01/04/2018

Eligibility

Key inclusion criteria

1. Age between 29-66 years
2. BMI between 29 and 40.99 kg/m²

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

438

Key exclusion criteria

1. Pregnancy (female participants only)
2. Behavioral eating disorders
3. Relevant gastrointestinal disease (ulcerating colitis, Crohn's disease, celiac disease, digestive

tract cancer)

4. Excessive alcohol consumption (>28 U or 280 g/week in men, > 17 U or 168 g/week in women)
5. Severe cardiovascular disease
6. Diabetes,
7. Polycystic ovary disease
8. Treatment with any medication that could alter insulin sensitivity or body weight (corticosteroids, antipsychotics, antidepressants)
9. Pharmacological treatment for clinical or subclinical hypothyroidism
10. Hyperthyroidism
11. Depression
12. Psychosis
13. Microalbumin/creatinine ratio >100 mg/g or stage IIIB or higher chronic kidney disease (glomerular filtration rate < 45 mL/min)
14. Use of medication requiring frequent dose adjustments
15. Low intellectual or mental functioning that could interfere with the participant's compliance with the recommendations
16. If the result of the glucose overload test is blood glucose ≥ 200 mg/dL the participant is excluded if the physician opts to add medication or insulin to the dietary and physical exercise regime.

Date of first enrolment

01/05/2014

Date of final enrolment

30/06/2017

Locations

Countries of recruitment

Spain

Study participating centre

Centro de Salud (CS) de La Victoria de Acentejo

C/Domingo Salazar 21

La Victoria de Acentejo

Spain

38380

Study participating centre

CS La Matanza de Acentejo

Carretera General del Norte

Ermita

La Matanza de Acentejo

Spain

38370

Study participating centre

CS Santa Úrsula

C/Calvo Sotelo s/n

Santa Ursula

Spain

38390

Study participating centre

Consultorio La Perdoma

C/ Manuel Vega Santos, nº 7

La Orotava

Spain

38315

Study participating centre

CS Los Realejos

C/San Isidro nº 10

Los Realejos

Spain

38410

Study participating centre

CS Casco Botánico

Carretera Las Dehesas nº 8

Puerto de La Cruz

Spain

38400

Study participating centre

CS Tacoronte

Carretera General del Norte nº 5

Tacoronte

Spain

38350

Study participating centre

Consultorio La Esperanza

Carretera Sardinera s/n

La Laguna
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38290

Study participating centre
Consultorio Valle Guerra
C/Camino Las Toscas nº 4
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Study participating centre
CS Taco
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Study participating centre
CS Guimar
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CS Barranco Grande
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Study participating centre**CS Finca España**

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Study participating centre**Consultorio Igueste de Candelaria**

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Sponsor information

Organisation

Fundación Canaria de Investigación Sanitaria

ROR

<https://ror.org/03vhx9d88>

Funder(s)

Funder type

Government

Funder Name

Instituto de Salud Carlos III

Alternative Name(s)

SaludISCI, Instituto de Salud Carlos III, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, La misión del Instituto de Salud Carlos III (ISCI), ISCI

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Spain

Funder Name

Fundacion Caja Canarias

Funder Name

Fundación DISA: premios de investigación médica 2018

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and analysed during the current study will be available upon request from Santiago Domínguez-Coello (sdomcoe@gobiernodecanarias.org; sdominguezc@telefonica.net) once this study has been published. These datasets will be available at any time and will be anonymous. All the requirements will have to be motivated on specific scientific reasons which must be detailed.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/04/2020	06/05/2020	Yes	No
Protocol article	protocol	07/08/2017		Yes	No
Basic results		14/01/2018	14/01/2019	No	No
Basic results		03/12/2019	03/12/2019	No	No