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Relationship between a low fructose consumption and insulin resistance

Submission date
04/11/2016

Recruitment status
No longer recruiting

Registration date
15/11/2016

Overall study status
Completed

Last Edited
06/05/2020

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
sdomcoe@gobiernodecanarias.org

Contact information

Type(s)
Scientific

Contact name
Dr Santiago Dominguez Coello

ORCID ID
http://orcid.org/0000-0003-1974-1936

Contact details
Gerencia de Atención Primaria de Tenerife
Servicio Canario de Salud.
Calle Carmen Monteverde nº 45
Santa Cruz de Tenerife
Spain
38003
+34 (0)922 581 900
sdomcoe@gobiernodecanarias.org

Type(s)
Scientific

Contact name
Dr Jesus Gobierno Hernandez

Contact details
Consultorio el Escobonal
Plaza San Jose S/N
El Escohonal-Güimar
Spain
38591
+34 (0)822 171 816
jgobierno@gmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ISCIII 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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

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

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 measure
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.

Secondary outcome measures
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

Overall study start date
31/05/2012

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

Age group
Adult

Sex
Both

Target number of participants
245 in each group

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
Spain
38290

Study participating centre
Consultorio Valle Guerra
C/Camino Las Toscas nº 4
La Laguna
Spain
38290

Study participating centre
CS Taco
C/Moisés Alberto s/n
Santa Cruz de Tenerife
Spain
38108

Study participating centre
CS Guimar
C/Poeta Hernández Mora s/n
Güimar
Spain
38500

Study participating centre
CS Barranco Grande
Calle Ruiseñor, s/n
Santa Cruz de Tenerife
Spain
38107

Study participating centre
CS Ofra Delicias
Avenida Príncipes de España 7A
Santa Cruz de Tenerife
Spain
38310

Study participating centre
CS Toscal-Centro
C/Ruiz de Padrón 6
Santa Cruz de Tenerife
Spain
38002

Study participating centre
CS Finca España
Carretera General Santa Cruz-Laguna nº 141
La Laguna
Spain
38201

Study participating centre
Consultorio Igueste de Candelaria
C/ Ajoreña 0
Candelaria
Spain
38520

Sponsor information

Organisation
Fundación Canaria de Investigación Sanitaria

Sponsor details
Barranco La Ballena s/n
CIF: G76208396
La Palmas de Gran Canaria
Spain
35019

+34 (0)922 679 123
aparache@funcanis.org

Sponsor type
Research organisation

Website
www.funcanis.org

ROR
https://ror.org/03vhx9d88

Funder(s)

Funder type
Government

Funder Name
Instituto de Salud Carlos III

Alternative Name(s)
SaludISCIII, InstitutodeSaludCarlosIII, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, ISCIII

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

Publication and dissemination plan
Planned publication of the study protocol immediately once the trial is registered. This protocol details how all foods and nutrient contents were obtained. Planned submission of the results for publication during the first months of 2019.

Intention to publish date
01/04/2019

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?
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
Results article	results	19/04/2020	06/05/2020	Yes	No