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Investigating the effect of Plantago psyllium fiber supplementation on levels of cholesterol and inflammation in adolescents with obesity

Submission date
17/08/2020

Recruitment status
No longer recruiting

Registration date
24/08/2020

Overall study status
Completed

Last Edited
19/04/2021

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Obesity can lead children and adolescents to have an increased risk of developing cardiovascular disease (CVD). A diet supplemented with Plantago psyllium (a type of fiber from the Plantago ovata plant's seeds) has been shown to be effective in reducing certain markers of blood cholesterol and inflammation in adolescents. However, there are no studies that have explored small-dense low-density lipoprotein (sdLDL) nor high-density lipoprotein (HDL) subclasses of cholesterol. The aim of this trial is to assess the impact of a fiber supplement on cholesterol in adolescents with obesity.

Who can participate?
100 adolescents, aged 15 to 19 years old, with obesity will be included in the study.

What does the study involve?
Eligible participants will be randomly allocated to recieve either the Plantago psyllium supplement or an identical dummy pill. These will be taken, dissolved in water, daily over a period of 7 weeks in the morning before food.

What are the possible benefits and risks of participating?
The benefits are the performance of free laboratory tests such as glucose, lipid profile such as cholesterol, triglycerides, insulin and lipoprotein profile with the sub-fractions of HDL and LDL (sdLDL), together with a clinical medical evaluation, which will contribute to the prevention of possible diseases and suggestion of healthy dietary recommendations.

The risks and discomfort that the patient may have are allergy or intolerance to the treatment, an increase in the number of evacuations, and abdominal distension. These side effects would be corrected when the treatment is suspended. Participants or their family members will be advised to suspend treatment if they experience any of these symptoms, and the trial team will determine if any further specific management for the symptoms is needed.

Taking the blood sample involves only the risk of a bruise, which will take between one and two weeks to disappear from the puncture site.

Where is the study run from?
Universidad de Guanajuato (Mexico)

When is the study starting and how long is it expected to run for?
From February 2017 to March 2020

Who is funding the study?
The University of Guanajuato (Mexico) and Touro University (USA)

Who is the main contact?
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Contact information

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CIBIUG-P40-2017

Study information

Scientific Title
Reduction of small dense LDL and Il-6 after intervention with Plantago psyllium in adolescents with obesity

Acronym
sdLDLpsyllium

Study objectives
Supplementation with Plantago psyllium alone decreases the concentration of sdLDL and inflammation markers (IL-6) in the population at risk such as adolescents with obesity

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 03/08/2018, University of Guanajuato (Calzada de Guadalupe S/N, Zona centro, Guanajuato Gto., México CP 36000; +52 473 73 200 06 ext. 5019); ref: CIBIUG-P40-2017
2. Approved 26/10/2018, Hospital de Gineco-pediatría No. 48 (Av. México e Insurgentes S/N colonia Los insurgentes, León Gto., México CP 37238; +52 477 7-17-48-00), ref: R-2018-1002-052

Study design
Single centre, double-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
School

Study type(s)
Prevention

Participant information sheet
Not available in web format please contact patipili999@hotmail.com to request participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular disease in adolescents with obesity

Interventions
This study was a randomized placebo-controlled trial with a double-blinded (to the participant and the investigator who gave the treatment) design.

Randomization and allocation to trial group were done using computer random number generation.

All participants were randomized into a 7 week intervention with either 10 g/day of psyllium (equating to 10 g of dietary fiber) Plantago psyllium powder (Kirkland signature ®, Lot 0294B12), or 10 g/day of rice flour placebo (Healthy Flours ® batch AB140119). In both groups, the dose was diluted in 250 ml of water, ingested immediately after dilution with intake of 250 ml of additional water, in the morning, before ingesting food.

The dose of 10 g/day was adopted based on a review of the existing literature, as well as on the volume of fiber and placebo each dose would equate to, so as not to affect compliance with the study protocol.

Both the psyllium and rice flour were packed in opaque bags without labeling the name only as A or B. Each dose was given daily by the blinded investigator.

Adherence to dosing was monitored directly through a checklist and during the weekend through a photograph sent by the participant through What'sApp. Participants were advised to continue their normal eating and exercise patterns during the study period. Three dietary records were collected at baseline and at clinical assessment following the 7 week intervention. Each dietary report encompassed an itemized nutritional intake recorded during two school days and one weekend day. Nutritional intake was recorded using standard household measures, as well as the information from food labels where appropriate. At each visit during the dietary treatment phase, the participants were asked about possible adverse effects or intolerance to psyllium or placebo using an open-ended questionnaire referring to any unusual symptoms or discomfort or side effects such as increased defecation, bloating, flatulence or fullness during the treatment period.

Intervention Type
Supplement

Primary outcome measure
1. Anthropometric and biochemical markers measured using the following at baseline and 7 weeks:
1.1. The height and weight of the child measured using a SECA stadiometer (to the nearest 0.1 cm) and a SECA scales (to the nearest 0.1 kg), and body mass index (BMI) was calculated as

kilogram per square meter (kg/m2)
1.2. Waist circumference (WC) measured using Lufkin ® metallic tape (to the nearest 1mm)
1.3. LDL and HDL subclasses measured using a venous blood sample obtained after 12 h of fasting processed using the Lipoprint system (Quantimetrix)
1.4. IL-6 measured using an ELISA assay of a venous blood sample was obtained after 12 h of fasting

Secondary outcome measures
Somatometric variables measured using the following at baseline and 7 weeks:
1.1. Blood pressure measured using an Omron® digital baumanometer
1.2. Glucose measured using a venous blood sample obtained after 12 h of fasting processed using enzymatic methods in an autoanalyzer (Spinreact-Spinlab, Model 6002390-412-02)
1.3. Homeostatic Model Assessment of Insulin Resistance (HOMA IR) measured using an ELISA assay of a venous blood sample was obtained after 12 h of fasting
1.4. Lipid profile measured using a venous blood sample obtained after 12 h of fasting processed using enzymatic methods in an autoanalyzer (Spinreact-Spinlab, Model 6002390-412-02)
1.5. The atherogenic index (AI) calculated as total cholesterol/HDL-C using measurements from a venous blood sample obtained after 12 h of fasting processed using enzymatic methods in an autoanalyzer (Spinreact-Spinlab, Model 6002390-412-02) and the Lipoprint system (Quantimetrix)

Overall study start date
02/02/2017

Completion date
02/03/2020

Eligibility

Key inclusion criteria
1. Aged 15 to 19 years
2. ≥1 of the following cardiovascular risk factors:
2.1. Obesity, defined as a body mass index (BMI) for age more than 2 standard deviations above the median established in the World Health Organization (WHO) Child Growth Standards
2.2. Altered lipid profile, defined as: total cholesterol >70 mg/dl; LDL cholesterol >110 mg/dl; HDL cholesterol <40 mg/dl; fasting glucose >100 mg/dl; elevated triglycerides >90 mg/dl; or insulin resistance with Homeostatic Model Assessment of Insulin Resistance (HOMA IR) >3
3. Non-smokers

Participant type(s)
Other

Age group
Child

Lower age limit
15 Years

Upper age limit
19 Years

Sex
Both

Target number of participants
100

Total final enrolment
100

Key exclusion criteria
1. Do not agree to adhere to at least 80% of diet and fiber
2. Diagnosis of a metabolic and/or infectious disease during the study
3. Do not wish to continue in the study or unable to be located for follow up

Date of first enrolment
10/11/2018

Date of final enrolment
15/12/2019

Locations

Countries of recruitment
Mexico

Study participating centre
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Sponsor type
Hospital/treatment centre

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ROR
https://ror.org/03xddgg98

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Sponsor type
University/education

Website
http://www.ugto.mx/

ROR
https://ror.org/058cjye32

Funder(s)

Funder type
University/education

Funder Name
Universidad de Guanajuato

Alternative Name(s)
University of Guanajuato, College of the Immaculate Conception, National College of Guanajuato, UG

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Mexico

Funder Name
Touro University California

Alternative Name(s)
Touro University, TUC

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United States of America

Funder Name
Mining Company Santa María de la Paz

Results and Publications

Publication and dissemination plan
Planned publication in high-impact peer review journal

Intention to publish date
30/09/2020

Individual participant data (IPD) sharing plan
Data sets generated and/or analyzed during the current study during this study will be included in the publication of subsequent results.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	01/08/2021	19/04/2021	Yes	No