ISRCTN15425217 https://doi.org/10.1186/ISRCTN15425217

Effect of flaxseed on fatty liver disease in adolescents

Submission date 20/07/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 29/07/2024	**Overall study status** Ongoing	[X] Statistical analysis plan [_] Results
Last Edited 29/07/2024	**Condition category** Digestive System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Fatty liver is the most common chronic liver disease worldwide. Improvements in diet and physical activity are first-line therapy. Flaxseed is rich in polyunsaturated fatty acids, proteins of high biological value and antioxidant nutrients. Multiple studies in the adult population have shown that flaxseed ingestion improves the nutritional, hepatic and fat profiles.
The aim of this study is to analyze the effect of flaxseed on the Controlled Attenuation Parameter in adolescents with fatty liver.

Who can participate?
Adolescent patients aged 10 to 17 years, of any sex, with a diagnosis of fatty liver (with a diagnosis established by evidence of hepatic steatosis by ultrasonography), who also have overweight or obesity according to the World Health Organization (WHO) .Patients whose parents have a mobile phone. Patients that receive follow-up in the outpatient clinic for nutrition, pediatric endocrinology and pediatric gastroenterology areas of the Instituto Mexicano del Seguro Social, Unidad Médica de Alta Especialidad No. 48, Hospital de Gineco Pediatría, Centro Médico Nacional del Bajío.

What does the study involve?
The patients will be assigned into one of the two group studies, using a table with random numbers. Group 1 will receive recommendations in changes of lifestyle that include orientation over diet and physical activity alongside a cookie with flaxseed, every 24 hours before breakfast, for 12 weeks. Group 2 will receive recommendations in changes of lifestyle that include orientation over diet and physical activity alongside a wheat bran cookie every 24 hours before breakfast, for 12 weeks. Both cookies contain the same amount of fiber and protein in each.They will provide the same amount of energy.
At the beginning the patients will receive a 20-minute educational session with dietary guidance and recommendations to maintain the same type of routine physical activity; the patient will receive this information in writing.
In week 0 and week 12, the Controlled Attenuation Parameter will be evaluated in the patients of both groups. In both weeks 0 and 12, the researcher will do some questions on the patient to evaluate the Food Security.
In weeks 0, 6 and 12, researchers will evaluate the BMI of the patients, waist circumference,

blood pressure and laboratory testing regarding the liver function, lipid profile and fasting glucose. The Frequency of Food Consumption survey will be applied on these patients at weeks 0, 6 and 12. On weeks 0, 6 and 12, a podometer will be given to patients to evaluate the amount of steps taken in a 5 day period.
After all the initial studies have been carried out, the patients will receive 1 weeks' worth of cookies that correspond to their group and an appointment will be made once a week to give them a new supply. Patients will be instructed to eat one cookie daily before breakfast for 12 weeks.
At the weekly visit, a brief questionnaire will be carried out to assess attachment to eating the cookie and the patient will be asked to return the closed box empty or with the remains if the patient has not eaten all the cookies.
Parents or tutors will receive a brief phone call each Tuesday and Saturday motivating them to eat the cookies, and they will be interrogated about the presence of symptoms like diarrhea, abdominal pain, among others.

What are the possible benefits and risks of participating?
The possible benefits of participating are the following: the patient will receive information through the measurements that will be carried out on them that will allow monitoring of existing diseases and this will also allow timely measures, receiving care from the necessary specialists for their management. In addition, patients will receive in their diet 9 grams of fiber per day and 6 grams of protein per day, which will be part of their daily requirement.
The possible risks are the following: taking measurements on the patient's body may cause them embarrassment by exposing their waist and abdomen. Taking a blood sample will cause pain that is considered mild and may leave a bruise. The intake of flaxseed or wheat bran in the quantities that will be given so far has no scientific evidence of any risk; however, it contains fiber so it can cause soft stools or abdominal pain. Researchers will monitor and, if necessary, will give medical attention, taking in consideration the suspension of the intake of these cookies.

Where is the study run from?
It will run at the Instituto Mexicano del Seguro Social, Unidad Médica de Alta Especialidad No. 48, Hospital de Gineco Pediatría, Centro Médico Nacional del Bajío, Street Paseo de los Insurgentes S/N, Col. Los Paraísos; at the city of León, from the state of Guanajuato, Mexico.

When is the study starting and how long is it expected to run for?
October 2023 to September 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Mariana Gómez Nájera, marianagomeznajera@gmail.com

Contact information

Type(s)
Principal Investigator

Contact name
Dr Mariana Gómez-Nájera

ORCID ID

https://orcid.org/0009-0009-3614-9572

Contact details
Street Bernese 108, Col. Lomas del Refugio
León
Mexico
37358
+52 4773526064
m.gomeznajera@ugto.mx

Type(s)
Public, Scientific

Contact name
Dr Gloria Patricia Sosa-Bustamante

ORCID ID
https://orcid.org/0000-0002-8460-4965

Contact details
Street Fersen 106, Col. Lomas del Refugio
León
Mexico
37358
+52 4773931426
gloria.sosa@imss.gob.mx

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effect of flaxseed on Controlled Attenuation Parameter in adolescents with Metabolic Dysfunction-Associated Steatotic Liver Disease. Controlled Clinical Trial

Acronym
EFLXCAPMASLD

Study objectives

The flaxseed has an effect on the controlled attenuation parameter in adolescents with metabolic dysfunction-associated steatotic liver disease.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/07/2024, Local Board of Health Research 1002 (Street Paseo de los Insurgentes S /N, Col. Los Paraísos, León, 37320, Mexico; +52 477 7174 800; 10028hgp48@gmail.com), ref: R-2024-1002-041

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Metabolic Dysfunction-Associated Steatotic Liver Disease in adolescents.

Interventions
The patients will be assigned into one of the two group studies, using a table with random numbers. Group 1 will receive recommendations in changes of lifestyle that include orientation over diet and physical activity alongside a cookie with flaxseed, every 24 hours before breakfast, for 12 weeks. Group 2 will receive recommendations in changes of lifestyle that include orientation over diet and physical activity alongside a wheat bran cookie every 24 hours before breakfast, for 12 weeks. Both cookies contain the same amount of fiber and protein in each.They' ll contribute the same amount of energy
At the beginning the patients will receive a 20-minute educational session with dietary guidance and recommendations to maintain the same type of routine physical activity; the patient will receive this information in writing.
In week 0 and week 12, the Controlled Attenuation Parameter will be evaluated in the patients of both groups. In both weeks 0 and 12, the researcher will do some questions on the patient to evaluate the Food Security.
In weeks 0, 6 and 12, researchers will evaluate the BMI of the patients, waist circumference, blood pressure and laboratory testing regarding the liver function, lipid profile and fasting glucose. The Frequency of Food Consumption survey will be applied on these patients at weeks 0, 6 and 12. On weeks 0, 6 and 12, a podometer will be given to patients to evaluate the amount of steps taken in a 5 day period.

After all the initial studies have been carried out, the patients will receive 1 weeks' worth of cookies that correspond to their group and an appointment will be made once a week to give them a new supply. Patients will be instructed to eat one cookie daily before breakfast for 12 weeks.
At the weekly visit, a brief questionnaire will be carried out to assess attachment to eating the cookie and the patient will be asked to return the closed box empty or with the remains if the patient has not eaten all the cookies.
Parents or tutors will receive a brief phone call each Tuesday and Saturday motivating them to eat the cookies, and they will be interrogated about the presence of symptoms like diarrhea, abdominal pain, among others.

Intervention Type
Other

Primary outcome measure
Controlled Attenuation Parameter will be measured with Fibroscan, at weeks 0 and 12

Secondary outcome measures
1. In weeks 0, 6 and 12, the nutritional profile will be evaluated with the BMI, waist circumference, blood pressure and laboratory testing regarding the liver function (ALT, AST, GGT, LDH), lipid profile (LDL, HDL, cholesterol, tryglycerides) and fasting blood glucose
3. The Daily Intake of Energy will be evaluated with the Frequency of Food Consumption Survey at weeks 0, 6 and 12
4. On weeks 0, 6 and 12, physical activity will be evaluated with a podometer that will assess the average of the amount of steps taken in a 5 day period
5. Presence of adverse effects will be evaluated with the presence of any gastrointestinal symptoms like diarrhea or abdominal pain

Overall study start date
01/10/2023

Completion date
01/09/2025

Eligibility

Key inclusion criteria
1. Adolescent patients, from ages 10 to 17, of any sex, with the diagnosis of Metabolic Dysfunction-Associated Steatotic Liver Disease
2. Adolescentes with an established diagnosis of Steatotic Liver disease by ultrasonography, presence of overweight or obesity according to the Z-score Z ≥1 BMI, with reference parameters of the WHO
3. Parents of the patient must have a phone number
4. Patients that receive follow-up at the outpatient consultation on the Nutrition, pediatric endocrinology and pediatric gastroenterology areas, at the Instituto Mexicano del Seguro Social, Unidad Médica de Alta Especialidad No. 48, Hospital de Gineco Pediatría, Centro Médico Nacional del Bajío

Participant type(s)
Patient

Age group
Child

Lower age limit
10 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Patients with the diagnosis of a previous Drug Induced Liver Injury, Viral Hepatitis B or C infection or HIV infection
2. Patients with alcohol ingestion greater than 140g per week in women or greater than 210g per week on men
3. History of Congenital hepatic disease, autoimmune diseases, primary hypothyroidism, psychiatric disorders or chronic kidney disease
4. Allergy to flaxseed or wheat
5. Patients treated with either one or more of the following medications: steroids, hypoglycemic agents, hypolipidemic agents, vitamin supplements, docosahexaenoic acid, eicosapentaenoic acid, antibiotics or herbal therapy
6. Patients with physical or sensorial disabilities
7. Pregnant or breastfeeding patients

Date of first enrolment
01/09/2024

Date of final enrolment
01/06/2025

Locations

Countries of recruitment
Mexico

Study participating centre
Instituto Mexicano del Seguro Social, Unidad Médica de Alta Especialidad No. 48, Hospital de Gineco Pediatría, Centro Médico Nacional del Bajío
Street Paseo de los Insurgentes S/N, Col. Los Paraísos
León
Mexico
37320

Sponsor information

Organisation
Mexican Social Security Institute

Sponsor details
Street Paseo de los Insurgentes S/N, Col. Los paraísos
León
Mexico
37320
+52 4777174800
gloria.sosa@imss.gob.mx

Sponsor type
Hospital/treatment centre

Website
http://www.imss.gob.mx/

ROR
https://ror.org/03xddgg98

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/11/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Mariana Gómez Nájera, at the following email address: marianagomeznajera@gmail.com

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	Data capture sheet		29/07/2024	No	No
Participant information sheet			29/07/2024	No	Yes
Statistical Analysis Plan			29/07/2024	No	No