Annex1 Participant information sheet

Letter of informed consent for participation in

Protocols of research in health

(Parents or legal representatives of minors or disabled persons)

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Place and date

No. of institutional registration_____

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

Justification and objective of the research:

Metabolic hepatic steatosis is a chronic and progressive disease that accumulates fat in the liver, treated with dietary recommendations and physical activity, but when these measures are not enough, it is important to consider other alternatives to improve the progressive changes in the liver.

The objective of this research is: To analyze the effect of flaxseed on the controlled attenuation parameter in adolescents with metabolic hepatic steatosis. This parameter is measured by special ultrasound equipment and counting with certain value confirms the presence of fat in the liver.

Procedures and duration of the investigation:

Once you agree to your child(s) participate, a distribution will be made into two groups 1 or 2, using a table with random numbers, the fate will decide in which group it will be. A group will receive lifestyle recommendations including dietary and physical activity guidance + flaxseed cookie every 24 hours before breakfast for 12 weeks. The other group will receive lifestyle recommendations that include dietary and physical activity guidance + wheat bran cookie every 24 hours before breakfast for 12 weeks. Both cookies contain fiber and protein in the same amount. They will provide a similar amount of energy.

Neither you nor MD. Mariana Gómez Nájera will know what kind of cookie your child will receive(a) Only a team investigator will know who will be tasked with making the closed boxes with the inside cookies that you will receive.

After knowing which group will be collected the following data name, date of birth, age, sex, allergies, clinic of adscription. Details of the parent or guardian: age, sex, mobile phone or landline, address, full schooling, occupation.

You will receive a 20-minute educational session with dietary guidance and recommendations to maintain the same type of routine physical activity, you will receive this information in writing.

In week 0 and week 12, your child(s) will be ultrasound to measure liver fat, for this lie on a stretcher and discover your abdomen, It has a transducer that is a plastic device that you put gel on and with this will be placed on your abdomen on the right side, to get images of the liver. The approximate time is 5 minutes, it's not painful.

In week 0 and 12, you will be asked questions to learn about the ease of getting food at home.
At week 0, 6 and 12 will be measured to your child(s) weight, height, with which BMI will be calculated, circumference of waist, blood pressure, and a 3 ml blood sample will be taken by means of a needle in your arm to make studies of liver function, sugar and blood fat.

In week 0, 6 and 12, questions will be asked about what your child(s) eats.

You will be given in week 0 a small device that will be placed on the waist, to measure your child's steps (a) during the day for 5 days (one of them must be Saturday or Sunday). You will be explained how to use it. This measurement will be repeated at week 6 and 12. Does not cause pain. At the end of the measurement, the apparatus shall be returned to MD. Mariana Gómez Nájera.

After all initial studies have been completed, you will receive a 1 week allowance of the cookies corresponding to your group and will be quoted once a week to deliver new allowance, You will be told to eat one cookie a day before breakfast for 12 weeks.

At the weekly visit a short questionnaire will be done to assess attachment to eating the cookie and you will be asked to return the box closed empty or with the remains in case you have not eaten all cookies.
You will receive (the parents or guardian brief) phone call Tuesday and Saturday motivating to comply with the consumption of these and will question about symptoms such as diarrhea or abdominal pain or others.

Risks and nuisances:

Taking measurements on your body can cause you to be shy or embarrassed by showing us your waist and abdomen. Taking a blood sample by using a stick on your arm will cause pain that is considered mild and may leave a bruise. The intake of flax or wheat bran in the amounts that will be granted so far has no scientific evidence of any risk, However, it contains fiber so it can cause soft bowel movements or abdominal pain. We will monitor and if necessary, receive medical attention and consider suspending the intake of the cookie.

Benefits you will receive by participating in the research:

You will receive information through the measurements to be made to your child(s) that will allow monitoring of existing diseases and this will enable timely measures, you will receive attention from the specialists necessary for its management. You will receive in your diet 9 grams daily of fiber and 6 grams daily of protein that will be part of your daily requirement.

Information on results and treatment alternatives:

The results shall be reported in a clear and timely manner. It will not interfere with your follow-up in specialties where you already have multidisciplinary management such as nutrition, endocrinology or gastroenterology.

Participation or withdrawal:

The participation is voluntary. At the time you wish to remove your child(s) from the project, feel free to do so. You have the right to accept or not, without this affecting the care in the medical areas of UMAE 48. You will not be denied medical care if you decide to withdraw or leave the study.

Privacy and confidentiality:

During the course of research and, if necessary, dissemination of results in scientific media (scientific medical journals); Researchers commit to maintain the privacy of all personal data that has been required for this study without any way of identifying or associating themselves with it. Your data will also not be transferred to another person other than the participants in this study.

In case of questions or clarifications related to the investigation, please contact:

Researcher or Lead Investigator:

Name: Mariana Gómez Nájera
Category: Non family Doctor.
Registration number: 99203111
Assignment: Unidad Médica de Alta Especialidad No. 48. Hospital de Gineco-Pediatría
Address: Paseo de los Insurgentes S/N Col. Los Paraísos. Leon, Guanajuato, Mexico.
Telephone: 477 7174800 Extension 31804 Hours Monday to Friday 8:00 to 13:00 hrs
E-mail: marianagomeznajera@gmail.com

Name: Catalina Peralta Cortázar.
Category: Non family Doctor.
Registration number: 99294662
Assignment: Unidad Médica de Alta Especialidad No. 48. Hospital de Gineco-Pediatría
Address: Paseo de los Insurgentes S/N Col. Los Paraísos. Leon, Guanajuato, Mexico.
Telephone: 477 3931426 and 477 7174800, Extension 31804. Opening hours Monday to Friday 14:00 to 20:00 hrs
E-mail: kta0614@yahoo.com.mx

In case of doubts or clarifications about your rights as a participant you may contact:
Local Committee of Ethics of Health Research of the CNIC of the IMSS: Avenida Cuauhtémoc 330 4° floor Block "B" of the Unit of Congresses, Colonia Doctores. Mexico, D.F., CP 06720. Telephone (55) 56 27 69 00, extension 21230, e-mail: comité.eticainv@imss.gob.mx. The UMAE 48 IEC 10028 to the e-mail: 10028hgp48@gmail.com

Declaration of consent:

	I accept that my relative or representative is given data or samples only for this study
	I accept that my relative or representative is taken the data or samples for this study and/or future studies

The **samples are kept** for up to ___2 years after which they are destroyed.

_____ _____

Name and signature of the parent or legal representative

Name and signature of the person obtaining consent

_____ _____

Name and signature of witness 1

Name and signature of witness 2

Annex 2 Child information sheet

Letter of consent in minors (8 to 17 years)

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Place and date

No. of institutional registration_____

Title of the protocol:

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

Research objective and procedures:

The objective of this research is to analyze the effect of flaxseed on the parameter of controlled attenuation in adolescents with metabolic hepatic steatosis. This parameter is measured by a special ultrasound equipment and having a certain value confirms the presence of fat in the liver.

Hello, my name is MD. Mariana Gómez Nájera and I work at the Mexican Social Security Institute. We are currently conducting a study to learn about the **effect of flaxseed on the on the controlled attenuation parameter in adolescents with metabolic hepatic steatosis** and for this we want to ask you to support us.

Your participation in the study would consist of: Once you agree to participate, a distribution will be made into two groups 1 or 2, using a random list, fate will decide which group you will be in.

A group will receive guidance on diet and physical activity + flaxseed cookie, every 24 hours before breakfast for 12 weeks.

The other group will receive the same orientation + wheat bran cookie every 24 hours before breakfast for 12 weeks. Both cookies contain fiber and protein in the same amount. Both have similar amounts of energy.

Your parents, you and I, MD. Mariana Gómez Nájera we will not know what kind of cookie you will receive only one of the team's investigators will know, who will deliver the boxes with the cookies inside. After knowing which group you will be in, we will collect data such as name, date of birth, age, sex, allergies, clinic of affiliation. Data of the parent or guardian such as name, age, sex, mobile phone, landline, address, full schooling, occupation.

They will receive your mother, father or guardian together with you, at the beginning of a 20-minute educational session with food guidance and recommendations to maintain the same type of physical activity, shall receive this information in writing.

Different studies will be conducted for a total of 12 weeks, I mention them below.
At the beginning and in week 12 a ultrasound to measure liver fat, for this you will lie down on a stretcher and you will discover your abdomen, it has a transducer, that it´s a plastic device that you put gel on and with this will be placed on your abdomen on the right side, to get images of the liver. The approximate time is 5 minutes, it's not painful.

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In week 0 and 12, questions will be asked to your mother, father or guardian about the ease of getting food at home.

At the beginning, in weeks 6 and 12 you will be measured your weight, size, with which will be calculated body mass index, measure your waist, blood pressure, and a blood sample of 3 ml, by putting a needle in your arm to do some liver, sugar and fat blood tests.

At the beginning, in weeks 6 and 12, questions will be asked about what you eat to your parents or guardian.
Your parents or guardian will be given a small device that will be placed on the waist, to measure your steps during the day, for 5 days (one of them must be Saturday or Sunday). It will explain how to use you and your mother, father or guardian. This measurement will be repeated at week 6 and 12. Does not cause pain. Once the measurement is complete, you will return the device to MD. Mariana Gómez Nájera.

After all initial studies have been completed, you will receive a 1 week supply of the cookies corresponding to your group and I will quote you once a week to deliver the new supply, and return the previous closed box empty or with the remains in case you did not eat them all. You should eat a daily pre-breakfast cookie for 12 weeks, it is important not to forget to do so.

During the weekly visit, a short questionnaire will be done to assess whether you are eating the cookie.
Your mom, dad or tutor will receive a short phone call on Tuesday and Saturday to motivate you to comply with the cookie consumption and I will ask them about adverse effects such as diarrhea or abdominal pain. We will monitor and in case of occurrence, if necessary you will receive medical attention and it will be considered to suspend the intake of the cookie.

Your participation in the study is voluntary, meaning that even if your dad or mom has said you can participate, if you don't want to do it, you can say no. It's your decision whether or not you participate in the study. It's also important that you know that if at any point you don't want to continue in the study, there won't be any problem, or if you don't want to answer a particular question, There won't be a problem.

This information shall be confidential. This means that we will not tell anyone your answers or results without you authorizing it, only the people who are part of the team in this study and your parents will know.

If you agree to participate, I ask that you please put one **(x)** in the square below that says "I want to participate" and write your name.
If **you don't want to participate, leave it blank and do no**t write your name.

☐ If I want to participate

Name: _____

Name and signature of person obtaining consent: _____