

Lifestyle programme in obese children with non-alcoholic fatty liver disease

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
05/02/2015	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
12/02/2015	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
09/08/2018	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims

There is evidence that family dietary education programmes are effective in children with obesity, but there is little evidence of this in children with non-alcoholic fatty liver disease (a build-up of fat in the liver cells). The aim in this study is to assess the effect of a nutritional counselling programme on hepatic abnormalities associated with non-alcoholic fatty liver disease in obese children.

Who can participate?

Children who are obese and have non-alcoholic fatty liver disease

What does the study involve?

Patients will have a clinical assessment and liver function tests at baseline and after 4 months of intervention. They will attend nutrition counselling sessions with their parents or guardians every 15 days.

What are the possible benefits and risks of participating?

The possible benefits are body-mass index reduction and improvement in the primary alterations in liver function associated with non-alcoholic fatty liver disease in obesity. Risks not provided at time of registration.

Where is the study run from?

Pediatric Hospital of the National Medical Center XXI Century (Mexico)

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

From October 2008 to December 2012

Who is funding the study?

National Council of Science and Technology (Mexico)

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

2006/3603/022

Study information

Scientific Title

Effect of lifestyle intervention in children with obesity and non-alcoholic fatty liver disease

Study objectives

The lifestyle of children with obesity and non-alcoholic fatty liver disease can improve with a lifestyle intervention programme

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics board of the Pediatric Hospital at the National Medical Center Century XXI of the Mexican Institute of Social Securite (Mexico), 02/05/2006, 37B5032500/232/06

Study design

Interventional single-centre study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Non-alcoholic liver disease

Interventions

From the start of the study and every 15 days thereafter during 4 months, both children and their parents in small groups had one-hour sessions conducted by a dietitian and a medical doctor. These sessions provided educational material about the importance of adequate food intake, with emphasis on lowering the amount of refined sugar and sugary sodas, reducing the amount of carbohydrates and fat consumed every day, and increasing the amount of fibre.

Intervention Type

Behavioural

Primary outcome(s)

At baseline and after 4 months of intervention:

1. Clinical evaluation
2. Liver function tests

Key secondary outcome(s)

Lipid profile at baseline and after 4 months of intervention

Completion date

14/12/2012

Eligibility

Key inclusion criteria

1. Age 6–16 years old
2. Obesity
3. Non-alcoholic fatty liver disease (ultrasound findings of steatosis, alanine aminotransferase > 40 U/L and alanine aminotransferase to aspartate aminotransferase ratio > 1)
4. No other cause of liver disease

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 years

Upper age limit

16 years

Sex

All

Key exclusion criteria

1. History of medication misuse
2. Alcohol misuse
3. Hepatitis C
4. Hepatitis B
5. Wilson's disease

Date of first enrolment

01/10/2008

Date of final enrolment

17/12/2010

Locations

Countries of recruitment

Mexico

Study participating centre

Pediatric Hospital of the National Medical Center XXI Century

Avenida Cuauhtémoc 330

Colonia Doctores

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Mexico

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Sponsor information

Organisation

Fondo para el Fomento de la Investigación en Salud

Funder(s)

Funder type

Government

Funder Name

Consejo Nacional de Ciencia y Tecnología (Mexico)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>	results	01/01/2017		Yes	No