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

Submission date
05/02/2015

Recruitment status
No longer recruiting

Registration date
12/02/2015

Overall study status
Completed

Last Edited
09/08/2018

Condition category
Nutritional, Metabolic, Endocrine

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

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Non-alcoholic liver dsease

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 measure
At baseline and after 4 months of intervention:
1. Clinical evaluation
2. Liver function tests

Secondary outcome measures
Lipid profile at baseline and after 4 months of intervention

Overall study start date
02/01/2006

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

Age group
Child

Lower age limit
6 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
46 patients

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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Sponsor information

Organisation
Fondo para el Fomento de la Investigación en Salud

Sponsor details
Mexican Institute of Social Securite
Avenida Cuauhtémoc 330
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Sponsor type
Research council

Funder(s)

Funder type
Government

Funder Name
Consejo Nacional de Ciencia y Tecnología (Mexico)

Results and Publications

Publication and dissemination plan
Publish the results in a journal with an impact factor

Intention to publish date
31/12/2015

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?
Results article	results	01/01/2017		Yes	No