

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of nutritional modification program on quality of life and liver-specific symptoms in children with chronic liver disease

Protocol summary

Summary

The objectives of this study was to determine the effects of diet on the quality of life of children with chronic liver disease is liver-specific. Simple random sampling from among those listed in the hospital HIS system Ghaem Mashhad is performed and then samples were assigned to two groups. The population of the clinical trial in children with chronic liver disease who were referred to the pediatric hospital Ghaem Mashhad last at least 6 months of disease, the lack of restrictions on the physical health, mental health and lack of restrictions ranging from age 2 to 18 years are. The demographic questionnaire, Peds QL 4.0, anthropometric studies are completed first. Blood samples were tested for albumin, prothrombin time, aspartate aminotransferase, alanine aminotransferase and bilirubin were taken. Both specialized and general nutritional guideline is developed by studying books and articles. Specialized guide guide researchers and the general guidelines for patient's guide (Be competent / and children). Then guide the patient in the form of a six-day work shop on the subjects taught. In the first two sessions, which were the subject of meetings liver disease, and its impact on both groups are fed. The third session only groups are present and prepared booklet about their diet in chronic liver disease received. And 4 other session workshop topics calculate the energy, carbohydrate, lipid calculation and calculation of protein, vitamins, and finally calculates the final practice session for the calculation of the booklet to receive daily regimens. workshop through face to face training, multimedia and practical work will be held. Workshops are held three days a week for two weeks. After the last workshop patients were followed for 12 weeks. Participants once a week during the first month and the second month in person every two weeks to assess adherence and physical examination by their investigator. RECALL 24-hour sessions are forms to be filled by competent care. The data is archived in the case of research. During this period, Telephone researcher is

competent to provide care in the event of a problem or need guidance with their call. At the end of 12 weeks of study, re-tools mentioned above are completed. After collecting data in order to comply with ethical principles, 4 the next session of the workshop booklet and follow-up three months after it was administered to the control group. 1. nutritional modification program, to improve the quality of life of children with chronic liver disease. (2) nutritional modification program, children with chronic liver disease decreased prothrombin time. 3. nutritional modification program, children with chronic liver disease increased albumin. 4. nutritional modification program, total bilirubin and direct children with chronic liver disease reduced. 5. The nutritional modification program, children with chronic liver disease and liver enzymes decreased.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015091424019N1**

Registration date: **2016-01-30, 1394/11/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-01-30, 1394/11/10

Registrant information

Name

Zahra Namjou

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 913 073 3270

Email address

namjooz911@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2014-06-10, 1393/03/20

Expected recruitment end date

2015-02-19, 1393/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of nutritional modification program on quality of life and liver-specific symptoms in children with chronic liver disease

Public title

Diet and children with chronic liver disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria for children: 1. Children with liver disease who are at least 6 months old disease 2. Iranian citizenship is a lie Mashhad. 3. patients tend to have the company study. 4. phone calls possible. 5. Children with chronic liver disease have other physical limitations. 6. children with chronic liver disease, mental health is not restricted. 7. aged 2 to 18 years old. Exclusion criteria related to children: 1. there is no desire to continue cooperation. 2. children to be fed TPN. 3. Children need to have a feeding tube. Inclusion criteria for the appropriate care: 1. The desire to have the company study. 2. Help is at least the third degree. 3 phone calls possible. Exclusion criteria for the appropriate care: 1. Randasht workshop is willing to continue cooperating companies

Age

From **2 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Mashhad University of Medical Sciences, Faculty of Nursing and Midwifery

Street address

Faculty of Nursing and Midwifery

City

Mashhad

Postal code**Approval date**

2014-05-07, 1393/02/17

Ethics committee reference number

922144

Health conditions studied**1****Description of health condition studied**

Chronic Liver Disease

ICD-10 code

K76.9

ICD-10 code description

Liver disease, unspecified

Primary outcomes**1****Description**

Quality of life

Timepoint

First and end of the study

Method of measurement

Questionnaire Peds ql 4.0

2**Description**

Prothrombin time

Timepoint

First and end of the study

Method of measurement

Values obtained from tests of Biochemistry

3**Description**

Albumin

Timepoint

First and end of the study

Method of measurement

Values obtained from tests of Biochemistry

4

Description

Bilirubin

Timepoint

First and end of the study

Method of measurement

Values obtained from tests of Biochemistry

5

Description

Aspartate aminotransferase

Timepoint

First and end of the study

Method of measurement

Values obtained from tests of blood

6

Description

Alanine amino transferase

Timepoint

First and end of the study

Method of measurement

Values obtained from tests of blood

Secondary outcomes

1

Description

Height

Timepoint

First and end of the study

Method of measurement

The value of the stadiometer

2

Description

Weight

Timepoint

First and end of the study

Method of measurement

The value of the bio-electrical impedance devices

3

Description

Body Mass Index

Timepoint

First and end of the study

Method of measurement

Body weight divided by the square of Height is achieved Index

Intervention groups

1

Description

Training was conducted in 6 sessions. In the first two sessions, which were the subject of meetings liver disease, and its impact on nutrition. 4 other meeting issues of energy consumption, carbohydrate, lipid calculation and calculation of protein, vitamins, and finally calculates the final practice session for the calculation of daily regimens, respectively

Category

Other

2

Description

Training was conducted over 2 sessions. Which were the subject of meetings liver disease, and its impact on nutrition

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Street address

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Department of Science and Technology of Mashhad
University of Medical Sciences

Full name of responsible person

Mohsen Tafaqodi

Street address

Third floor, Qureshi building, University Avenue,
Mashhad

City

Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Department of Science and Technology of Mashhad
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

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Person responsible for general inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty