Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

An efficacy and safety comparison study of Fenofibrate and omega 3 in pediatric patients with Hypertriglyceridemia, A Randomized Clinical Trial

Protocol summary

Study aim
Comparison of the effects and side effects of fenofibrate and omega-3 in children with hypertriglyceridemia

Design
The clinical trial has two intervention groups, with parallel groups, one-blind, randomized, on 60 patients, and SAS version 9 software is used for randomization with the method of 4 permutation blocks.

Settings and conduct
The study will be conducted in Rasht 17 Shahrivar hospital (endocrine department) in two intervention groups 1 and 2. The patients are not blind to the treatment group and are only researchers and statistics experts analyzing the information blind to the treatment group

Participants/Inclusion and exclusion criteria
Inclusion criteria: children 8 to 18 years old Higher triglyceride equal to 400mg/dl Lack of pregnancy, acute or chronic pancreatitis, acute hepatitis, sepsis No alcohol consumption Absence of liver, kidney and biliary diseases Also, children with total cholesterol higher than 200 mg/dl or LDL higher than 130 mg/dl who are being treated with statins or ezetimibe will not be included

Intervention groups
The first group receives fenofibrate 100 mg once a day along with diet and the second group receives 1000 mg omega-3 twice a day. The duration of the intervention is 12 weeks and all patients are monitored weekly and monthly by pediatric endocrinologists.

Main outcome variables
Fasting blood triglyceride

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220516054879N4**
Registration date: **2023-01-21, 1401/11/01**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-21, 1401/11/01**
Update count: **0**

Registration date
2023-01-21, 1401/11/01

Registrant information

Name
maryam shahrokhi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 13 3336 9026

Email address
mshahrokhi@gums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-21, 1401/11/01

Expected recruitment end date
2023-04-21, 1402/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
An efficacy and safety comparison study of Fenofibrate and omega 3 in pediatric patients with Hypertriglyceridemia, A Randomized Clinical Trial

Public title
An efficacy and safety comparison study of Fenofibrate and omega 3 in pediatric patients with

Hypertriglyceridemia, A Randomized Clinical Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

8-12 years old Patients with hypertriglyceridemia, with triglyceride more than 400mg/dl or triglyceride more than 250mg/dl that are intended to use medication or not responded to diet and exercise.

Exclusion criteria:

Patient reluctance Patient treated with statins or ezetimibe Pragnancy Acute or chronic pancreatitis

Age

From **8 years** old to **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Type of randomization, details of any restrictions (such as blocking and block size): To randomize people in two groups, permutation blocks (of 4) are used. Considering that group A is the recipient of fenofibrate and group B is the recipient of omega-3. The randomization process will be as follows. The entire randomization file is available as an Excel file (randomization was done with SAS software version 9).

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

Ethics Committee of Gilan University of Medical Sciences

Street address

Rasht-Namjo Street-Shahid Siadati Street-in front of 17 Shahrivar Hospital-Deputy for Research and Technology

City

Rasht

Province

Guilan

Postal code

4193713111

Approval date

2022-12-21, 1401/09/30

Ethics committee reference number

IR.GUMS.REC.1401.483

Health conditions studied

1

Description of health condition studied

Hypertriglyceridemia

ICD-10 code

E78.1

ICD-10 code description

Pure hyperglyceridemia, Endogenous hyperglyceridemia

Primary outcomes

1

Description

Fasting blood triglycerides

Timepoint

The variable will be measured at the beginning of the study, 8 and 12 weeks after the start of the study

Method of measurement

Blood tests

2

Description

Fasting blood LDL level

Timepoint

The variable will be measured at the beginning of the study, 8 and 12 weeks after the start of the study.

Method of measurement

Blood tests

3

Description

Fasting blood cholesterol

Timepoint

The variable will be measured at the beginning of the study, 8 and 12 weeks after the start of the study

Method of measurement

Blood tests

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group : In addition to following the diet, they also receive fenofibrate 100 mg once a day after lunch for 12 weeks.

Category
Treatment - Drugs

2

Description
Intervention group: In addition to following the diet, they also receive 1000 mg of omega-3 twice a day for 12 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
بیمارستان 17 شهریور
Full name of responsible person
مریم شاهرخی
Street address
Rasht - Namjo Street - Shahid Siyadati Street - 17 Shahrivar Hospital
City
Rasht
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4144654379
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+98 13 3336 9019
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Mshahrokhi@gums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Mohammadreza Naghipour
Street address
Rasht - Namjo Street - Shahid Siyadati Street - in front of 17 Shahrivar Hospita
City
Rasht
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Guilan
Postal code
4193713111
Phone
+98 13 3333 6394
Email
research@gums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Maryam Shahrokhi
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Medical pharmacy
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Rasht - Namjo Street - Shahid Siyadati Street - 17 Shahrivar Hospital
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Other areas of specialty/work
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Person responsible for updating data

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Guilan
Postal code
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Phone
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Email
parnianne75@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Preservation of patients' privacy and compliance with ethical principles
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The results of the study will be available to everyone. Exclusive information will be available only to the treatment staff. To respect the privacy of the patient, the patient's information will be kept by the researcher.
When the data will become available and for how long
Currently, there is no plan to publish the data, but if it is published, it will be 6 months after the results are published.
To whom data/document is available
Researchers who are active in this field, pediatric specialists and scientific and qualified people
Under which criteria data/document could be used
Doctors and researchers will have the right to request, there are restrictions in order to protect the patient's privacy and comply with medical ethics
From where data/document is obtainable
17 Shahrivar Hospital, Rasht - Dr. Maryam Shahrokhi, Faculty of Pharmacy, Gilan Medical Sciences - Parnian Nemati
What processes are involved for a request to access data/document
Go to 17 Shahrivar Hospital in Rasht and sign the application form, then meet with the researcher of the plan and review the application of the referring person, consult with the ethics committee in medicine and then submit the documents.
Comments