Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Study of Oral Liverghol Impact on Liver Enzymes in Patients with Thalassemia Major and Intermedia

Protocol summary

Study aim
Study of oral Liverghol impact on enzymes of liver in patients with major thalassemia and intermedia thalassemia .

Design
Clinical trial with a control group with parallel groups, two-blind, randomized.

Settings and conduct
This study was carried out as a clinical trial at the Pediatric Clinic of Amir Kabir Hospital in Arak on patients with thalassemia, also the study will also be two blinded in which patients and researcher will be blinded in study. This assessment is a clinical trial in Phase 3, the children who are diagnosed with thalassemia major and Intermedia and approved by a specialist physician are considered as a study group. In this study, 40 children who have entered the criteria are selected. Patients are categorized based on blocked randomization method, 20 children in the intervention group (recipient of the livergol) and 20 children in the control group (recipient of the placebo). Accordingly, the status of liver enzymes is evaluated initially and then monthly for 6 months after starting treatment.

Participants/Inclusion and exclusion criteria
Patients over 5 years of age with β-thalassemia major and intermedia referred to Amir Kabir hospital in Arak, with informed consent in the study, impaired hepatic enzymes (AST And ALT greater than 60), total cholesterol above 200, total bilirubin more than 2, and Gamma glutamyl transpeptidase more than 60 are enrolled in the study, also patients with other blood diseases and liver diseases such as HBV, HCV and HIV excluded from the study.

Intervention groups
In the intervention group, people aged below 12 years of age, 70 mg and over 12 years of age, 140 mg of livergol tablets for two times per day, in the control group, the same placebo is used two per day.

Main outcome variables
Liver Enzymes Level

General information

Reason for update
Change the method from one blinded to two blinded

Acronym

IRCT registration information
IRCT registration number: **IRCT20150119020715N9**
Registration date: **2019-01-17, 1397/10/27**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-20, 1398/09/29**
Update count: **1**

Registration date
2019-01-17, 1397/10/27

Registrant information

Name
Aziz Eghbali

Name of organization / entity
دانشگاه علوم پزشکی اراک

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-22, 1397/06/31

Expected recruitment end date
2019-07-22, 1398/04/31

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of Oral Liverghol Impact on Liver Enzymes in Patients with Thalassemia Major and Intermedia

Public title

Evaluation Liverghol Impact on Liver Enzymes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients over 5 years of age with β-thalassemia Major and Intermedia referring to Amir Kabir hospital in Arak Informed consent of the participants in the study Disrupted liver enzymes (AST and ALT greater than 60). Total cholesterol above 200 Total bilirubin equal to or greater than 2 GGT more than 60

Exclusion criteria:

With other blood diseases and liver diseases such as HBV, HCV and HIV

Age

From **5 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomization is done with sealed envelope tools in such a way that the letters A and B are inserted in the envelopes and patients are asked to select an envelope that the intervention group A and the group B they will be tested

Blinding (investigator's opinion)

Double blinded

Blinding description

This means that patients in groups and researcher do not know the used drugs, and drugs has similar packaging, two drugs are similar in color, two drugs are similar in taste and odor.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Sardasht

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2018-11-30, 1397/09/09

Ethics committee reference number

IR.ARAKMU.REC.1397.109

Health conditions studied

1

Description of health condition studied

Thalassemia Major and Intermedia

ICD-10 code

D56

ICD-10 code description

Thalassemia

Primary outcomes

1

Description

Liver Enzymes

Timepoint

Before treatment, with a month's interval in six month from starting treatment

Method of measurement

Blood tests

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In cases under 12 years of age take 70 mg and over 12 years of age take 140 mg of Liverghol oral pills two times per day, for 6 months.

Category

Treatment - Drugs

2

Description

Control group: The same placebo take two times per day, for 6 months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Pediatrics, Amir Kabir hospital

Full name of responsible person

Roghaie Rahimi Afzal

Street address

Amir Kabir hospital, Basij Square, Arak.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Ali Arash Anoushirvani

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Vice Chancellor for Research, Arak University of Medical Sciences, Sardasht, Arak.

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Aziz Eghbali

Position

Blood specialist and oncology

Latest degree

Subspecialist

Other areas of specialty/work

Blood and Oncology Diseases

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Subspecialist

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Person responsible for updating data

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Subspecialist
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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
No more information
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available