Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Evaluation the efficacy of Livergol(Sylimarin extract) on liver function of thalassemia major and intermedia patients: A triple-blinded, randomized, placebo-controlled trial

Protocol summary

Study aim

This study aims to investigate the effect of Sylimarin extract on liver function in patients with major thalassemia and intermedia thalassemia

Design

Concealed, randomized, triple blinded, phase 3 controlled clinical trial with two arm parallel group design of 80 patients, using the placebo in the control group.

Settings and conduct

This study will be performed in Abureyhan Specific Diseases Center in Bandar Abbas city. Patients enter the study after obtaining written consent. Patients are randomly assigned to one of the intervention or control groups with the placebo. Moreover, patients,care provider and investigators will not know which group they belong to. (tripple blinded)

Participants/Inclusion and exclusion criteria

Confirmed thalassemia major and intermedia cases by a specialist physician who have ALT > 2 times of upper normal limit ,iron overload (serum ferritin of 1000-5000ng/l) during 6 months before the study,negative CRP and signs the written consent of the study will be included in the study. Patients will be excluded from the study if they have a history of hepatitis B and C virus infection,HIV positive test,chronic kidney disease,irreversible cirrhosis,symptoms of portal vein hypertension or refuse to participate in the study.

Intervention groups

In the intervention group, people aged under12 years, 70 mg(one tablet)and over 12 years of age, 140 mg(two tablets) of Livergol for three times per day, in the control group, the same placebo is used three times per day.

Main outcome variables

Aspartate aminotransferase (AST) , alanine aminotransferase (ALT) and ferritin levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220424054645N1**
Registration date: **2022-05-18, 1401/02/28**
Registration timing: **prospective**

Last update: **2022-05-18, 1401/02/28**
Update count: **0**

Registration date

2022-05-18, 1401/02/28

Registrant information

Name

Zahra Ghaeini Hesarooeyeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2023-04-19, 1402/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation the efficacy of Livergol(Sylimarin extract) on liver function of thalassemia major and intermedia patients: A triple-blinded, randomized, placebo-controlled trial

Public title
Effect of Livergol in treatment of thalassemia major and intermedia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Confirmed thalassemia major and intermedia cases with CBC and HB electerophoresis Patients without anaphylactoid reactions to any medication Patients with ALT rising more than two times of upper normal limit Consent to participate in trial Iron overload(serum ferritin of1000-5000ng/l) during 6 months before study Negative CRP

Exclusion criteria:
Hepatitis B or C virus infection HIV positive test Chronic kidney disease Thalassemia major patients with irreversible cirrhosis including 1-hyperglycemia 2-hyperalbuminemia 3-coagulopathy (INR> 1.5 and platelets <15000) Symptoms of increased portal vein pressure include ascites, esophageal varices, splenomegaly Research units have not tendency to continue the study

Age
From **1 year** old to **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple,Block

Blinding (investigator's opinion)
Triple blinded

Blinding description
All participants are aware of participating in this study and enter the study with their consent.The participant , care provider and investigators do not know which box contains placebo tablets and which contains Livergol tablets.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Hormozgan universuty of medical sciences

Street address
Clinical Research Development Center of Children's Hospital, Hormozgan University of Medical Sciences, Bandar Abbas,Hormozgan Province

City
Bandarabbas

Province
Hormozgan

Postal code
7916613885

Approval date
2022-04-30, 1401/02/10

Ethics committee reference number
IR.HUMS.REC.1401.024

Health conditions studied

1

Description of health condition studied
Thalassemia

ICD-10 code
D56

ICD-10 code description
Thalassemia

Primary outcomes

1

Description
Ferritin

Timepoint
Before intervention and 12 weeks after intervention

Method of measurement
Blood tests

2

Description
ALT

Timepoint
Before intervention and 12 weeks after intervention

Method of measurement
Blood tests

3

Description
AST

Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Blood test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In cases under 12 years of age take one tablet(70 mg)and over 12 years of age take two tablets(140 mg) of Livergol oral pills ,product of Goldaru pharmaceutical company, three times per day, for 3 months.
Category
Treatment - Drugs

2

Description
Control group: The same placebo ,product of pharmaceutical company,take three times per day, for 3 months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Abureyhan Specific Diseases Center
Full name of responsible person
Dr.Amir Hesabi
Street address
Educational,Research andTherapeutic Center of Children's Hospital, Northern Golshahr,Imam Khomeini Boulevard, Bandar Abbas
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Bandare-abbas 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
Bandare-abbas University of Medical Sciences
Full name of responsible person
Zahra Ghaeini Hesarooeyeh
Position
Student of Medicine
Latest degree
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Other areas of specialty/work
General Practitioner
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Person responsible for scientific inquiries

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Position
Assistant Professor

Latest degree
Subspecialist

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Hematology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

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