

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Evaluation of the effect of oral proliveon liver function in patients with major and intermediate thalassemia

Protocol summary

Study aim

The effect of oral prolio on hepatic parameters, patients with thalassemia major, and intremedia is determined.

Design

Double blind randomized clinical trial in Amir Kabir hospital in Arak. 40 patients with thalassemia major and Intermedia will be divided into two equal groups using block randomization method.

Settings and conduct

This clinical trial study will be performed on all patients with major beta-thalassemia over 5 years referred to Amir Kabir hospital. At baseline, liver enzymes levels of ALT, AST, total cholesterol, total protein, ALKp, total bilirubin and GGT will be measured by ELISA method. patients will be randomly divided into two groups. In the experimental group, the patients with age under 12 will receive half tablet and patients over 12 years will receive one tablet (275 mg) of oral Prolio twice daily (every 12 hours) and the placebo group will receive two placebo tablet twice daily. Patients will be treated 6 months and each month liver function tests will be performed. Then the information will be recorded.

Participants/Inclusion and exclusion criteria

in :All patients with beta thalassemia major and intermedia over 5 years Exit: Unwilling to participate

Intervention groups

At baseline, liver enzymes levels of ALT, AST, total cholesterol, total protein, ALKp, total bilirubin and GGT will be measured by ELISA in the control group. In the experimental group, patients under the age of 12 years will receive half a tablet and over 12 years one oral tablet (275 mg) of Prolio every 12 hours and in the control group patients will receive placebo control twice daily.

Main outcome variables

Hepatic parameters

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191010045050N1**

Registration date: **2020-01-05, 1398/10/15**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-05, 1398/10/15**

Update count: **0**

Registration date

2020-01-05, 1398/10/15

Registrant information

Name

Azam Ebrahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3312 7359

Email address

azame7733@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-01, 1398/09/10

Expected recruitment end date

2020-02-29, 1398/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of oral proliveon liver function in patients with major and intermediate thalassemia

Public title

Evaluation of the effect of oral prolive on liver function in patients with major and intermediate thalassemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with beta thalassemia major and intermedia over 5 years

Exclusion criteria:

Patients not willing to participate in the study Malignancy Liver dysfunction

Age

From **5 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Block Randomization Unit:
Individual Randomization Tool: Envelope Method How to Build a Random Sequence: Using
www.randomization.com Explanation of concealment:
Using non-transparent sealed envelopes with a random sequence

Blinding (investigator's opinion)

Double blinded

Blinding description

Only the researcher in this study will be aware of the study groups while the patients will be not aware of the type of drug being used. Also, the intern responsible for filling the checklists will be not aware of the type of medication consumed, and only will know the groups based on A and B and will fill out the checklists accordingly.

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

Arak University of Medical sciences ,Basij square , Sardasht

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2019-08-04, 1398/05/13

Ethics committee reference number

IR.ARAKMU.REC.1398.087

Health conditions studied

1

Description of health condition studied

Major and intermedia thalassemia

ICD-10 code

D77

ICD-10 code description

Other disorders of blood and blood-forming organs in diseases classified elsewhere

Primary outcomes

1

Description

Liver enzyme

Timepoint

Before the intervention and after, every one month to six months

Method of measurement

Laboratory

2

Description

Total Billirubin and Total protein

Timepoint

Before the intervention and after, every one month to six months

Method of measurement

Laboratory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: At baseline, liver enzymes levels of ALT, AST, total cholesterol, total protein, ALKp, total bilirubin and GGT will be measured by ELISA in the control group. patients with age under 12 will receive half tablet and patients over 12 years will receive one tablet (275 mg) of oral Prolio twice daily (every 12 hours) and repeat tests up to 6 months each months.

Category

Treatment - Drugs

2

Description

Control group: At baseline, liver enzymes levels of ALT, AST, total cholesterol, total protein, ALKp, total bilirubin and GGT will be measured by ELISA in the control group. patients will receive two placebo tablet twice daily (every 12 hours) and repeat tests up to 6 months each month.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Kabir Hospital in Arak

Full name of responsible person

Azam Ebrahimi

Street address

Nursing square , Shahid Shirodi street

City

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Email

Rsearch@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

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Email

Rsearch@arakmu.ac.ir

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

Azam Ebrahimi

Position

Medical Student

Latest degree

A Level or less

Other areas of specialty/work

Pediatrics

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91 Alley - Emam Khomeini Street

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Azam Ebrahimi

Position

Intern

Latest degree

A Level or less
Other areas of specialty/work
Pediatrics
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Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Azam Ebrahimi
Position
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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