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 Commitee of Arak University of Medica sciences
Street address
Arak University of Medica 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 thallassemia
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
Arak

Province
Markazi

Postal code
3848176941

Phone
+98 86 3313 4715

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

Street address
Arak Medical Science

City
Arak

Province
Markazi

Postal code
3848176941

Phone
+98 86 3313 4715

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

Street address
91 Alley - Emam Khomeini Street

City
Esfahan

Province
Isfehan

Postal code
8139949551

Phone
+98 86 3312 7359

Email
azame7733@gmail.com

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

Street address

Alley 91 - Emam khomeini street

City

Esfahan

Province

Isfehan

Postal code

8139949551

Phone

+98 86 3312 7359

Fax

Email

www.azame7733@gmail.com

Person responsible for updating data

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

Street address

Alley 91 - Emam khomeini street

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Fax

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www.azame7733@gmail.com

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