Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of oral L-arginine supplementation on improvement of cardiovascular function and pulmonary artery pressure in patients with major and Intermedia beta-thalassemia

Protocol summary

Study aim

The effect of L-arginine supplementation on improving pulmonary pressure in patients with beta thalassemia

Design

A clinical trial study with a control group with a parallel and double-blind randomized group on 88 patients

Settings and conduct

Patients with beta thalassemia major and transfusion-dependent intermediate media over 15 years of age Referred to Ali Asghar Hospital for treatment Based on the criteria measured in echocardiography and diagnosis of a cardiologist Patients with increased pulmonary artery pressure (PHTN) (pulmonary artery pressure above 25 mm Hg at rest) Identified and studied. 44 of these patients received oral L-arginine supplements in oral vials Another 44 people took placebo in the form of an oral vial similar to the main drug It is given over a period of two months And after 8 weeks to evaluate the effect of this supplement in both groups Echocardiography and cardiac re-examination are performed.Selection of patients are randomization and double-blind (patient and distributor and analyzer ...)

Participants/Inclusion and exclusion criteria

Patients with pulmonary artery pressure above 25 mm Hg at rest have been identified are included in the study. Patients with severe heart disease who need specialized measures and treatments Or have already been treated with heart medication, Patients with severe liver and kidney disease, diabetics, pregnant and lactating women And people who have been taking protein supplements for the last 6 months will be excluded from the study

Intervention groups

In 44 of these patients, oral L-arginine supplement in the form of oral vials and Another 44 people are given placebo in the form of an oral vial similar to the original medicine

Main outcome variables

Age. Gender. Ferritin level. Hemoglobin . History of splenectomy. Chelator drug used. Frequent transfusions .Ejection Fraction and PHTN before and after intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210220050430N1**
Registration date: **2021-05-07, 1400/02/17**
Registration timing: **prospective**

Last update: **2021-05-07, 1400/02/17**
Update count: **0**

Registration date

2021-05-07, 1400/02/17

Registrant information

Name

maryam shamspour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2262 2847

Email address

maryam.shams2744@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-20, 1400/02/30

Expected recruitment end date

2021-11-21, 1400/08/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of oral L-arginine supplementation on improvement of cardiovascular function and pulmonary artery pressure in patients with major and Intermedia beta-thalassemia

Public title
The effect of oral L-arginine supplementation on improvement of cardiovascular function and pulmonary artery pressure in patients with major and Intermedia beta-thalassemia
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Beta thalassemia major Above 15 years Thalassemia intermedia
Exclusion criteria:
Pregnancy Diadetes Sever kidney disease Sever liver disease Sever cardiac disease History of taking this supplement
Age
From **15 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **88**
Randomization (investigator's opinion)
Randomized
Randomization description
Random sampling is simple in that the names of all patients of thalassemia over 15 years is written and 88 people, which is equivalent to the sample size, will be selected by lot and Permuted- Block randomization are divided into two groups 8 blocks consisting of 4 participants in the intervention group and 4 participants in the control group. Block randomization is one of the limited randomization methods and is a Double-blind study
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the drug and placebo were labeled by the manufacturer Group A and Group B. Which are quite similar in appearance and the person participating in the study and the person distributing the medicine does not know about this labeling
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Medical scool of Iran university of medical sciences
Street address
Medical school of Iran university , Next Milad tower . Hemat highwey . Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2020-11-21, 1399/09/01
Ethics committee reference number
IR.IUMS.FMD.REC.1399.641

Health conditions studied

1

Description of health condition studied
Betha thalasemia
ICD-10 code
D56.1
ICD-10 code description
Beta thalassemia

Primary outcomes

1

Description
Pulmonary hypertension
Timepoint
2 month
Method of measurement
Echocardiography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Give oral vial L-arginine supplement made by iranian bio fermentation company with dose 0.1

gr /kg divided 2 or 3 time for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: give oral vial placebo made by iranian bio fermentation company similer to the main drug contain oral glucose for 8 week

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali asghar Pediatric of Hospital

Full name of responsible person

Shahla Ansai damavandi

Street address

No .193 . Aliasghar- Pediatric of Hospital. Hematology clinic . .Dastgardi street, North Modares highwey . Tehran . Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Abas Motevalian

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Dr .Shahla Ansari damavandi

Position

Pediatric Hematology and Oncology Specialist

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Latest degree

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Person responsible for updating data

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Position
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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
Confidentiality of patient information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available