

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 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

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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 Diabetes 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 school of Iran university of medical sciences

Street address

Medical school of Iran university , Next Milad tower . Hemat highway . Tehran, Iran

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Province

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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**

Beta thalassemia

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 similar 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 highway .
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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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Person responsible for scientific inquiries

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Latest degree

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Person responsible for updating data

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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