

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigation of the effect of oral L-arginine on pulmonary hypertension in patients with thalassemia major

Protocol summary

Study aim

Overall purpose: Determination the effect of oral L-arginine on pulmonary hypertension in patients with thalassemia major Specific purposes: Determination and comparison of PAP levels before and after the intervention Determination and comparison of systemic blood pressure before and after the intervention Determination and comparison of right ventricular dysfunction before and after the intervention Determination and comparison of TAPSE C before and after the intervention

Design

All 50 patients with thalassemia referred to the thalassemia clinic of Hajar hospital in Shahrekord will be included in the study if pulmonary hypertension and patient satisfaction are present. Due to the limitation of the sample size, this study was designed as a pre- and post-test. Due to the lack of control group, this study was not blinded.

Settings and conduct

Thalassemia Clinic of Hajar Hospital, Shahrekord

Participants/Inclusion and exclusion criteria

Inclusion criteria: Major or intermedia thalassemia with PAP> 30 Systemic blood pressure above 90/60 Not taking blood pressure lowering medications No use of Sildenafil and Bosentan Exclusion criteria: Allergic reaction to L-arginine Smoking Systemic blood pressure drops to less than 90/60 Liver, kidney and thyroid diseases

Intervention groups

All 50 patients with thalassemia referred to the thalassemia clinic of Hajar hospital in Shahrekord will be included in the study if pulmonary hypertension and patient satisfaction are present.

Main outcome variables

If L-arginine decreases PAP in thalassemic patients, this supplement may be used daily to improve the patient's cardiorespiratory status.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191218045785N1**

Registration date: **2020-01-18, 1398/10/28**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-18, 1398/10/28**

Update count: **0**

Registration date

2020-01-18, 1398/10/28

Registrant information

Name

Lale Najar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3222 0016

Email address

najarlale@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-13, 1398/02/23

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of oral L-arginine on pulmonary hypertension in patients with thalassemia major

Public title
Investigation of the effect of oral L-arginine on pulmonary hypertension in patients with thalassemia major

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Major or intermedia thalassemia with PAP> 30 Systemic blood pressure over 60/90
Exclusion criteria:

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: 50

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrekord University of Medical Sciences

Street address

University of Medical Sciences headquarters , Kashani Ave.

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Approval date

2019-05-12, 1398/02/22

Ethics committee reference number

IR.SKUMS.REC.1398.046

Health conditions studied

1

Description of health condition studied

Beta thalassemia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pulmonary arterial pressure

Timepoint

Baseline (before intervention) and 6 and 30 days after L-arginine administration

Method of measurement

Echocardiography

Secondary outcomes

1

Description

Systemic blood pressure

Timepoint

Baseline (before intervention) and 6 and 30 days after L-arginine administration

Method of measurement

Blood pressure monitor

Intervention groups

1

Description

Intervention group: Fifty patients with thalassemia major or intermedia are selected based on inclusion criteria. Due to the limited sample size, this study was designed as a pre- and post-test. All patients were initially echocardiographically diagnosed for pulmonary hypertension and systemic blood pressure was recorded. Patients are then given oral L-arginine capsules of 50 mg / kg daily divided into 3 doses. Echocardiography and systemic blood pressure measurements are performed again on the first, sixth day, and at the end of the first month.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Thalassemia Clinic of Hajar Hospital, Shahrekord

Full name of responsible person

Dr Kiavash Fekri

Street address

Parastar Ave.

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816854633

Phone

+98 38 3222 0016

Email

k.fekri@skums.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

Vice chancellor for research, Shahrekord University of Medical Sciences

Street address

Headquarter of Shahrekord Medical University

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Phone

+98 38 3333 0061

Email

info@skums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahre-kord 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**

Shahre-kord University of Medical Sciences

Full name of responsible person

Lale Najar

Position

Pediatric resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Department of Pediatrics , Hajar hospital , Parastar Ave.

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Phone

+98 38 3222 0016

Fax**Email**

najarlale@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

Lale Najar

Position

Pediatric resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Department of Pediatrics , Hajar hospital , Parastar Ave.

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Phone

+98 38 3222 0016

Fax**Email**

najarlale@gmail.com

Person responsible for updating data

Contact**Name of organization / entity**

Shahre-kord University of Medical Sciences

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Postal code

8815713471

Phone

+98 38 3222 0016

Fax**Email**

najarlale@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