

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Comparison of the effects of valsartan versus sildenafil on pulmonary arterial pressure in thalassemia major and intermedia patients with pulmonary hypertension

Protocol summary

Summary

The aim of this study is to compare the effects of valsartan with sildenafil on treatment of increased pulmonary arterial pressure in thalassemia major and intermediate patients who suffer from pulmonary hypertension. Valsartan has direct effects on cardiac systolic and diastolic function which could reduce pulmonary arterial pressure. It would be a new pathway in the treatment of pulmonary hypertension in such patients and would be helpful to improve their quality of life. In this study 100 known cases of thalassemia major and intermediate in Firuzgar hospital which have pulmonary arterial pressure more than 25 mmhg, will be included in the study. Patients will be excluded if any adverse drug reaction occurs or if the dyspnea will be worse. Fifty patients will receive valsartan and the next 50 will receive sildenafil. Patients will be followed via echocardiography (three times) and cardiac indexes will be measured during six months and will be compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012100611022N1**

Registration date: **2012-12-09, 1391/09/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-12-09, 1391/09/19

Registrant information

Name

Mohamad Namvar

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-10-22, 1391/08/01

Expected recruitment end date

2012-11-21, 1391/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of valsartan versus sildenafil on pulmonary arterial pressure in thalassemia major and intermedia patients with pulmonary hypertension

Public title

Valsartan therapy in the treatment of thalassemia-induced dyspnea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: thalassemia intermedia or major, age ≥ 10 years, systolic pulmonary artery pressure \geq mmhg25. Exclusion criteria: Allergy to sildenafil or valsartan, incidence the side effects of drugs, no consent

to continue the study, using other drugs which are in interaction with study drugs, increased NYHA function class of dyspnea

Age

From **10 years** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committee of Tehran University of Medical Sciences

Street address

Central Building of Tehran University of Medical Sciences, Qods st, Enghelab Sq, Tehran

City

Tehran

Postal code**Approval date**

2012-10-02, 1391/07/11

Ethics committee reference number

18147-30-02-91

Health conditions studied**1****Description of health condition studied**

secondary Pulmonary hypertension due to the Thalassemia

ICD-10 code

I27.2

ICD-10 code description

Other secondary pulmonary hypertension

Primary outcomes**1****Description**

Pulmonary arterial pressure

Timepoint

begining of the study, the last day of first month and the last day of 6th month

Method of measurement

Echocardiography

Secondary outcomes**1****Description**

Dyspnea

Timepoint

begining of the study, the last day of first month and the last day of 6th month

Method of measurement

NYHA function class

Intervention groups**1****Description**

Group 2 patients (as Intervention) will take valsartan drug 20 mg PO daily for six months.

Category

Treatment - Drugs

2**Description**

Group 1 patients (as control) will take Sildenafil drug 25 mg PO twice per day for six months.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Firuzgar hospital

Full name of responsible person

Dr Behzad Farahani

Street address

Firuzgar hospital, Beh Afarin St, Valiasr Sq, Tehran, Iran.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

School of medicine- Tehran University of Medical Sciences

Full name of responsible person

Dr Shahin Akund zadeh (Research deputy)

Street address

Central building of Tehran University of Medical Sciences, Qods St, Enqelab Sq, Tehran, Iran.

City

Tehran

Grant name

هنوز بودجه ای تصویب نشده است

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

Yes

Title of funding source

School of medicine- Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr Behzad Farahani

Position

Assistant professor of cardiology

Other areas of specialty/work**Street address**

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Medical student

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty