Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

Phone

+98 21 4406 3741

Email address

s-raeisi@student.tums.ac.ir

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 ≥ 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

Assisstant professor of cardiology

Other areas of specialty/work

Street address

Firuzgar hospital, Beh Afarin St, Vali asr Sq, Tehran

City

Tehran

Postal code

Phone

+98 21 8214 1334

Fax

Email

bh25391fr@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Behzad Farahani

Position

Assisstant professor of cardiology

Other areas of specialty/work

Street address

Firuzgar hospital, Beh Afarin St, Vali asr Sq, Tehran

City

Tehran

Postal code

Phone

+98 21 8214 1334

Fax

Email

bh25391fr@yahoo.co

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohamad Namvar

Position

Medical student

Other areas of specialty/work

Street address

Firuzgar hospital, Beh Afarin St, Vali asr Sq, Tehran

City

Tehran

Postal code

Phone

+98 21 8214 1334

Fax

Email

Web page address

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