

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the efficacy of Tadalafil versus Placebo on pulmonary artery systolic pressure and right ventricular function in patients with beta-thalassemia intermedia

Protocol summary

Summary

5-Phosphodiesterase inhibitors (PDE5Is) like sildenafil or tadalafil are used in treatment of Pulmonary Arterial Hypertension by decreasing vascular tonicity and inducing vasodilation. This study is designed to evaluate tadalafil effect in decreasing pulmonary arterial pressure and eventually improvement in right ventricular function in patients with major and intermedia beta thalassemia. Inclusion criteria (All of the following) : age more than 15 years ; major beta thalassemia patients or Intermedia beta thalassemia patients ; Pulmonary Arterial Hypertension or Right Ventricular Dysfunction. Exclusion criteria (One of the following) : age< 15 years ; using nitrates and alpha blockers (except Tamsulosin) at the time of the study ; minor beta thalassemia patients. This study is a double-blind and will be conduct in parallel for 6 weeks. Before intervention, the patients are evaluated by Ttransthoracic Echocardiography and their pulmonary arterial pressure and function and size of right ventricle are measured. Then, they are randomly divided to two intervention and control groups with 25 members and receive a drug (a daily single dose of tadalafil 40 mg capsule) or placebo (a similar capsule with similar administration to intervention group). After 6 weeks, all patients are evaluated again with the same Transthoracic Echocardiography system and their pulmonary artery pressure and function and size of right ventricle are measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013102715178N1**

Registration date: **2013-11-23, 1392/09/02**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-11-23, 1392/09/02

Registrant information

Name

Rozita Jalalian

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

1- Babol University of Medical Sciences, Research and Technology Assistance2- Project Executer

Expected recruitment start date

2013-12-01, 1392/09/10

Expected recruitment end date

2014-01-16, 1392/10/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of Tadalafil versus Placebo on pulmonary artery systolic pressure and right ventricular function in patients with beta-thalassemia intermedia

Public title

Effects of tadalafil on cardiovascular function in patients with thalassemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria (All of the following) : age more than 15 years ; major beta thalassemia patients (significant anemia, Hb< 7 and transfusion dependent) or Intermedia beta thalassemia (milder anemia, Hb between 7 and 10 and usually not transfusion dependent) ; Pulmonary Arterial Hypertension or Right Ventricle Dysfunction. Pulmonary Arterial Hypertension : mean pulmonary arterial pressure more than 25 mmHg at rest or more than 30 mmHg in activity (measured by transthoracic echocardiography). Right ventricular dysfunction as increase in right ventricle end-diastolic dimension (base> 4cm, midpart> 3.5) or decrease in function and ejection fraction of right ventricle according to TAPSE index (lesser than 2cm) and S index (lesser than 11cm) measured by transthoracic echocardiography. Exclusion criteria (One of the following) : age< 15 years ; using nitrates and alpha blockers (except Tamsulosin) at the time of study ; minor beta thalassemia patients

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Babol University of Medical Sciences, Research and Technology Assistance

Street address

University Sq, Ganj Afroz Av, Babol

City

Babol

Postal code

Approval date

2013-08-27, 1392/06/05

Ethics committee reference number

3012

Health conditions studied

1

Description of health condition studied

Major and Intermedia Beta Thalassemia

ICD-10 code

D56.1

ICD-10 code description

Beta thalassaemia, Thalassaemia: intermedia major

2

Description of health condition studied

Pulmonary Arterial Hypertension

ICD-10 code

I27.2

ICD-10 code description

Other secondary pulmonary hypertension

Primary outcomes

1

Description

Mean pulmonary arterial pressure

Timepoint

Once before beginning of intervention and once 6 weeks after beginning of intervention(At the end of intervention)

Method of measurement

With Transthoracic echocardiography system(CYE-Vivid3)- with doppler, color doppler, m mode, 2d and tissue doppler Modalities.

2

Description

Right ventricular end-diastolic dimension

Timepoint

Once before beginning of intervention and once 6 weeks after beginning of intervention(At the end of intervention)

Method of measurement

With Transthoracic echocardiography system(CYE-Vivid3)- with 2D modality

3

Description

Right ventricular function

Timepoint

Once before beginning of intervention and once 6 weeks after beginning of intervention(At the end of intervention)

Method of measurement

With Transthoracic echocardiography system(CYE-

Vivid3)- with M mode modality(for TAPSE) and Tissue doppler modality(for S)

Secondary outcomes

empty

Intervention groups

1

Description

Patients in control group get single daily dose of placebo capsules similar in weight and appearance to tadalafil 40 mg for 6 weeks.

Category

Placebo

2

Description

Patients in intervention group receive a single daily dose of tadalafil (40 mg capsules) for 6 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Roohani Hospital

Full name of responsible person

Street address

Ganj Afrooz Av, Babol

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences, Research and Technology Assistance

Full name of responsible person

Dr. ali Bijani

Street address

University Sq, Ganj Afrooz Av, Babol

City

Babol

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Babol University of Medical Sciences, Research and Technology Assistance

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

No organization (Project Executer)

Full name of responsible person

Dr. Rozita Jalalian

Street address

The Fifth Floor, Pars Complex, In front of Beheshti Hospital, Keshvari Sq, Babol

City

Babol

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

No organization (Project Executer)

Proportion provided by this source

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Roohani Hospital

Full name of responsible person

Dr. Rozita Jalalian

Position

Cardiologist, Fellowship of Echocardiography/
Assistant professor

Other areas of specialty/work

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Name of organization / entity

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Full name of responsible person

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Position

Medical Student

Other areas of specialty/work

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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