

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Sildenafil and ventriculo-arterial coupling in Fontan palliated patients. A noninvasive echocardiographic assessment

Protocol summary

Summary

To evaluate the impact of oral sildenafil on the ventriculo-arterial coupling in patients with Fontan circulation, we assessed a sample of 24 patients palliated with Fontan circulation in Children's Medical center. Patients included should have stable condition in the past 6 months and were excluded in case of heart, hepatic or renal failure and sensitivity to sildenafil. Clinical characteristics and echocardiographic examination of ventricular and arterial elastances were performed before and after a one week course of sildenafil 0.5mg/kg/q8h. Moreover we monitored the possible side effects of sildenafil throughout the course of therapy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202209092N1**

Registration date: **2012-04-30, 1391/02/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-04-30, 1391/02/11

Registrant information

Name

Reza Shabanian

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-03-20, 1389/12/29

Expected recruitment end date

2012-01-21, 1390/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Sildenafil and ventriculo-arterial coupling in Fontan palliated patients. A noninvasive echocardiographic assessment

Public title

Impact of sildenafil on the ventriculo-arterial performance in fontan palliated patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients aged ≥ 8 years with Fontan modification of ECTCPC, patients had NYHA function class of I, being stable for the past 6 months without the occurrence of new symptoms or any changes in their medication. Exclusion criteria: pulse oxymetry of $< 80\%$, systolic blood pressure of < 75 mmHg, hepatic and renal dysfunction confirmed by laboratory examination, ophthalmic and auditory defect, hypersensitivity to sildenafil, Fontan pathway obstruction detected by CT/MR imaging or angiography and recent use of sildenafil in the past 3 months, patients with residual cardiovascular defects such as coarctation, cardiac dysrhythmia or bradycardia, pregnant patients

Age

From **8 years** old to **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **23**

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**

Research Deputy.Tehran University of Medical Sciences,

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sixth floor ,Tehran university central organization, Ghods street ,Keshavarz Boulevard,tTehran,Iran

City

Tehran

Postal code**Approval date**

2012-04-16, 1391/01/28

Ethics committee reference number

130/2648/90/3

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

congenital heart disease circulatory disease

ICD-10 code

I97.1

ICD-10 code description

Other functional disturbances following cardiac surgery

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

elastance

Timepoint

at the onset and one week post sildenafil administration

Method of measurement

echocardiography

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

headache, flushing,vertigo,nausea and vomiting, abdominal pain, renal stone, photosensitivity,rash,diarrhea ,hypotension, muscle pain,tinnitus

Timepoint

at the onset and one week post sildenafil administration and surveillance of side effects during the one week period of study

Method of measurement

queries

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

sildenafil 0.5mg/kg/q8hours for one week

Category

Treatment - Drugs

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

Children's Medical Center

Full name of responsible person

Reza Shabanian

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Children's Medical Center, 62,Gharib street,r,Tehran,Iran

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr Shahin Akhondzadeh

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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
 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

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Person responsible for updating data

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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