Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 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, hypersensivity to sildenafil, Fontan pathway obstruction detected by CT/MR imaging or angiography and recent use of sildenafi 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
Researdh Deputy.Tehran University of Medical Sciences,
Street address
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/د

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, photosensivity,rash,diarrhea ,hypotension, musle pain,tinnitus
Timepoint
at the onset and one week post sildenafil administration and surviellance 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
Street address
Children's Medical Cente, 62,Gharib street,r,Tehran,Iran
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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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Research Deputy , Medical 0f Faculty,Tehran University of Medical Science,Poorsina Street, Ghods Street, Tehran,Iran
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Tehran

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
Name of organization / entity
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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