Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of Sildenafil Pharmacokinetic Properties in Long-term Treatment of Pediatrics Pulmonary Hypertension

Protocol summary

Summary

Objective: to access pharmacokinetic profile of Sildenafil in long-term therapy of pediatric Pulmonary arterial hypertension (PAH). Thirty patients with PAH who refer to the pediatric heart clinic in Sari will be included. Inclusion criteria: 1) patients aged 1 month to 12 year. 2) mean pulmonary artery pressure of ≥ 25 mm Hg and a normal pulmonary capillary wedge pressure (PCWP). Exclusion criteria: 1) using other vasodilators such as epoprostanol, bosentan. 2) patients with systemic blood pressure <50% for the same age. The treatment duration is 16 weeks. Echocardiography is considered for all of patients before and 1 to 4 month after the beginning of therapy to determine related indexes. The initial dose is 0.5 mg/kg every 12 hours and can be increase up to 1 mg/kg every 6 hours. A serum sample is obtained when the clinical response appears. Serial samples are collected from 10 cases at 0.5, 1, 2, 4 h after using drug and just before the next dose.

General information

Acronym

SPPPH

IRCT registration information

IRCT registration number: **IRCT138805222342N1**
Registration date: **2009-10-09, 1388/07/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2009-10-09, 1388/07/17

Registrant information

Name

Mohammad Reza Rafati

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences (Vice-Chancellor for research)

Expected recruitment start date

2009-09-02, 1388/06/11

Expected recruitment end date

2010-03-01, 1388/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Sildenafil Pharmacokinetic Properties in Long-term Treatment of Pediatrics Pulmonary Hypertension

Public title

Evaluation of Sildenafil in Treatment of Pediatrics Pulmonary Hypertension

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) patients aged 1 month to 12 year 2) mean pulmonary artery pressure of ≥ 25 mm Hg and a normal pulmonary capillary wedge pressure (PCWP). Exclusion criteria: 1) using other vasodilators such as epoprostanol, bosentan 2) patients with systemic blood pressure <50% for the same age

Age
From **1 year** old to **12 years** old
Gender
Both

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **30**
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
Vice-Chancellor of Research, Mazandaran university of medical sciences
Street address
Moallem square
City
Sari
Postal code
4817844718
Approval date
2009-06-24, 1388/04/03
Ethics committee reference number
44-88

Health conditions studied

1

Description of health condition studied
pediatric pulmonary hypertension
ICD-10 code
127.0
ICD-10 code description
Primary pulmonary hypertension

Primary outcomes

1

Description
Reduction of pulmonary hypertension
Timepoint
1 month
Method of measurement
Echocardiography

Secondary outcomes

1

Description
Adverse drug reactions
Timepoint
1 month
Method of measurement
Question and exam

Intervention groups

1

Description
only intervention group, it bigins 0.5 mg/kg q12 hr and can increase up to 1 mg/kg q6hr weekly.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Boali hospital
Full name of responsible person
Street address
City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Vice-Chancellor of Research (Dr. Seid Jalal Hosseinimehr)
Street address
Moallem square
City
Sari
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Arash Badiee

Position

Pharmacy student

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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