

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the Effect of Sildenafil Nutrition on the Treatment of Injection Routine (Milirinone) in Infants with Pulmonary Hypertension

Protocol summary

Study aim

Evaluation of the effect of oral sildenafil addition to injection routine (milirinone) in infants with pulmonary hypertension

Design

A non- randomized, double-blind, placebo-controlled clinical trial. This study will be performed on 80 patients with pulmonary hypertension .These people are non-random are divided into two groups of 40 people using minimization method and minim software.Control group and group receiving oral sildenafil

Settings and conduct

This study will be carried out in the neonatal ward of Afzalipour Hospital. In the first phase, 80 patients will be divided into control and intervention groups Using non-minimizing method with minim software.In the intervention group, oral sildenafil was given in combination with injectable milrinone and in the control group only injectable milrinone was administered 72 hours later, both groups will have echocardiography

Participants/Inclusion and exclusion criteria

Inclusion criteria included: neonates admitted to neonatal ward of Afzalipour Hospital, gestational age of 34 weeks or more, confirmation of high blood pressure diagnosis by echocardiography, and parental consent, and exclusion criteria included congenital heart disease and major abnormalities at birth

Intervention groups

In the intervention group sildenafil (3 mg per kg daily) with milirinone and in the control group only injectable milirinone The echocardiography is performed and re-echocardiography is performed 72 hours later for both groups

Main outcome variables

Changes in the treatment process and improvement of pulmonary hypertension

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190731044393N1**

Registration date: **2019-10-04, 1398/07/12**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-04, 1398/07/12**

Update count: **0**

Registration date

2019-10-04, 1398/07/12

Registrant information

Name

Maryam Ebrahimpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3325 7000

Email address

maryamebrahimpour1373@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-01, 1398/06/10

Expected recruitment end date

2020-08-31, 1399/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Sildenafil Nutrition on the Treatment of Injection Routine (Milirinone) in Infants with Pulmonary Hypertension		Kerman	
Public title		Province	
Evaluation of the Effect of Sildenafil Nutrition on the Treatment of Injection Routine (Milirinone) in Infants with Pulmonary Hypertension		Kerman	
Purpose		Postal code	
Treatment		7616913911	
Inclusion/Exclusion criteria		Approval date	
Inclusion criteria:		2019-05-29, 1398/03/08	
Infants hospitalized in neonatal wards of Afzalipour Hospital Parental Satisfaction Gestational age greater than or equal to 34 weeks Confirmation of diagnosis of high blood pressure by echocardiography		Ethics committee reference number	
Exclusion criteria:		IR.KMU.AH.REC.1398.038	
Congenital heart disease The birth of a major anomaly		Health conditions studied	
Age		<u>1</u>	
From 1 day old to 28 days old		Description of health condition studied	
Gender		Pulmonary hypertension	
Both		ICD-10 code	
Phase		I27.0	
3		ICD-10 code description	
Groups that have been masked		Primary pulmonary hypertension	
- Participant - Outcome assessor		Primary outcomes	
Sample size		<u>1</u>	
Target sample size: 80		Description	
Randomization (investigator's opinion)		Evidence of pulmonary hypertension	
Not randomized		Timepoint	
Randomization description		The first day and 72 hours later	
Blinding (investigator's opinion)		Method of measurement	
Double blinded		Eco cardiography	
Blinding description		Secondary outcomes	
In this study, drug interventions are considered and infants' parents will be blinded to the type of neonatal treatment And to evaluate the neonatal pulmonary pressure, an out-of-group evaluator is used to evaluate the type of blind treatment.		empty	
Placebo		Intervention groups	
Not used		<u>1</u>	
Assignment		Description	
Parallel		Intervention group: In the intervention group sildenafil (3 mg / kg / day) is given with milrinone	
Other design features		Category	
Secondary Ids		Treatment - Drugs	
empty		<u>2</u>	
Ethics committees		Description	
<u>1</u>		Control group: In control group only injectable milrinone is prescribed	
Ethics committee		Category	
Name of ethics committee		Treatment - Drugs	
Ethics Committee of Kerman University of Medical Sciences		Recruitment centers	
Street address		<u>1</u>	
Ibn Sina Street,Jihad Boulevard		Recruitment center	
City		Name of recruitment center	
		Afzalipour Kerman Hospital	
		Full name of responsible person	

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Dr. Abbas Payakhti
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City
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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

Kerman University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Maryam Ebrahimpour
Position

Infant Fellowship
Latest degree
Specialist
Other areas of specialty/work
Pediatrics
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to

make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available