

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Comparison of high and low doses of captopril in congestive heart failure (CHF) with left to right shunt

Protocol summary

Summary

This is a comparative prospective study on two different doses of captopril on congestive heart failure in newborn infants. This study is going to be done on 20 newborn infants in Nemazee hospital suffering congestive heart failure due to left to right shunt following congenital heart disease. Doppler Echocardiography will be done on day one and three and clinical evaluation done using Rose Score after the third day of treatment with Digoxin and Lasix. The patients are blindly divided in two groups for two different doses of captopril, 0.03mg/kg and 0.3mg/kg respectively. After 7 days the two groups will be evaluated clinically and with Doppler echo cardiographically. In the second and third evaluation the serum level of rennin and Aldostrone will be checked.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012072910441N1**

Registration date: **2013-01-11, 1391/10/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-01-11, 1391/10/22

Registrant information

Name

Narjes Pishva

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1612 5481

Email address

pishvan@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz university of medical sciences; Neonatology Research Center

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2012-06-20, 1391/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of high and low doses of captopril in congestive heart failure (CHF) with left to right shunt

Public title

Comparison of high and low doses of captopril in congestive heart failure (CHF) with left to right shunt

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: congenital heart disease with left to right shunt. Exclusion criteria: Trisomy 21, congenital anomalies including cleft lip and cleft palate esophageal atresia.

Age

From **1 year** old to **30 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 20

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz university of medical sciences

Street address

Zand street

City

Shiraz

Postal code

71937-11354

Approval date

2011-11-24, 1390/09/03

Ethics committee reference number

ct-90-5808

Health conditions studied

1

Description of health condition studied

congenital heart disease

ICD-10 code

Q20.9

ICD-10 code description

Congenital malformation of cardiac chambers and connections, unspecified

Primary outcomes

1

Description

The effect of captopril

Timepoint

The first, third and 7th day of treatment

Method of measurement

Rose score, Echocardiography

Secondary outcomes

1

Description

Serum Renin and Aldostron

Timepoint

The 7th day

Method of measurement

Renin and Aldostron level and Echocardiography

Intervention groups

1

Description

captopril, 0.03mg/kg for 7 days

Category

Treatment - Drugs

2

Description

Captopril, 0.3mg/kg for 7 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

NICU of Nemazee Hospital

Full name of responsible person

Dr. Narjes Pishva

Street address

Nemazee Hospital, Zand street

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz university of medical sciences

Full name of responsible person

Dr. Hatam

Street address

building of university of medical science 7th floor,
dean of research, Zand street

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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
Shiraz university of medical sciences
Full name of responsible person
Dr. Saeed Alinejad
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Fellowship of neonatology
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Hamid Amoozgar; Narjes Pishva
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Associate professor of pediatric; professor of pediatric
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Person responsible for updating data

Contact

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researcher
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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