

# 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  
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## Person responsible for scientific inquiries

### Contact

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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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Marzieh Dashtpeyma  
**Position**  
researcher  
**Other areas of specialty/work**  
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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*