

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### Use of Thiamine supplementation versus placebo on the cardiac function in chronic heart failure patients

#### Protocol summary

##### Summary

We hypothesized that Thiamine supplementation could significantly reduce the signs and symptoms of congestive heart failure (CHF) and improve the cardiac function as evaluated by conventional echocardiography. In this double blinded randomized controlled trial, 44 CHF patients will be divided into 2 equal groups to receive 300 mg/day oral thiamine or placebo. Every subject will undergo a thorough physical examination with respect to cardiovascular symptoms and transthoracic echocardiography. Patients of each group will be checked at 1 and 6 months for any changes in the CHF related symptoms and also echocardiographic features will be checked at these time points. At the end of the trial, the changes in signs, symptoms, clinical findings and also echocardiographic evaluations will be compared between the groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201311019768N2**

Registration date: **2013-11-12, 1392/08/21**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-11-12, 1392/08/21

##### Registrant information

###### Name

Akbar Shafiee

###### Name of organization / entity

Tehran Heart Center, Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8802 9256

###### Email address

shafiee@leydenacademy.nl

###### Recruitment status

**Recruitment complete**

###### Funding source

Tehran University of Medical Sciences

###### Expected recruitment start date

2013-04-01, 1392/01/12

###### Expected recruitment end date

2014-03-01, 1392/12/10

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Use of Thiamine supplementation versus placebo on the cardiac function in chronic heart failure patients

###### Public title

Use of Thiamine supplementation versus placebo on the cardiac function in chronic heart failure patients referred to the cardiology clinic of Imam Khomeini Hospital

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion: Consent to take part in the study; Treatment with Furosemide; Known case of congestive heart failure with ejection fraction < 40% and at least one of these criteria: 1- Dyspnea or orthopnea, 2- Positive hepatojugular reflux, 3- Interstitial transudation in the chest X-ray, 4- Brain natriuretic peptide (BNP)  $\geq$  39 ng/L. Exclusion: 1- Acute heart failure; Vitamine supplementation at the time of first visit; Renal insufficiency (serum creatinine > 250 micromol/L;

pregnancy.

### Age

From **18 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **44**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethical committee of Imam Khomeini Hospital, Tehran  
University of Medical Sciences

##### Street address

Keshavarz Blvd, Dr. Gharib st

##### City

Tehran

##### Postal code

##### Approval date

2013-05-19, 1392/02/29

##### Ethics committee reference number

309-130-92-3

## Health conditions studied

### 1

#### Description of health condition studied

Congestive Heart Failure

#### ICD-10 code

I50.0

#### ICD-10 code description

Congestive heart disease

## Primary outcomes

### 1

#### Description

Ejection fraction increase

### Timepoint

1 month and 3 months after recruitment

### Method of measurement

Echocardiography

## Secondary outcomes

### 1

#### Description

Improvement in the clinical symptoms

#### Timepoint

1 and 3 months after recruitment

#### Method of measurement

Interview and physical examination

## Intervention groups

### 1

#### Description

300 mg Thiamine daily as a single oral tablet

#### Category

Treatment - Drugs

### 2

#### Description

Similar tablet in shape containing placebo. once daily,  
oral

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Hospital

##### Full name of responsible person

Reza Rahmani

##### Street address

Keshavarz Blvd, Dr. Gharib St.

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Imam Khomeini hospital, Tehran University of Medical  
Sciences

##### Full name of responsible person

Reza Rahmani

##### Street address

Keshavarz blvd, Dr. Gharib st

##### City

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Imam Khomeini hospital, 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**

Tehran Heart Center, Tehran University of Medical Sciences

**Full name of responsible person**

Akbar Shafiee

**Position**

MD, MSc

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

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Tehran University of Medical Sciences

**Full name of responsible person**

Fatemeh Nemati

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Resident of Cardiology

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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*