

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### The effects of growth hormone (GH) on the results of echocardiography in patients with heart failure (HF) four weeks after myocardial infarction (MI)

#### Protocol summary

##### Summary

The aim of this study is to assess the effects of growth hormone on echocardiographic findings in 32 patients with heart failure, 4 weeks after myocardial infarction (MI). These patients after going through different stages and checking out inclusion criteria, will be divided into two groups of 16. One group for three months, every other day, and each patient will receive 5.0 mg of growth hormone and the second group received placebo in the same way. Echocardiography was undertaken three months later and was repeated again after three month. Then collected data will be analyzed by SPSS software.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201704083035N1**

Registration date: **2017-07-05, 1396/04/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-07-05, 1396/04/14

##### Registrant information

###### Name

Masoumeh Sadeghi

###### Name of organization / entity

Cardiovascular Research Institute, Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3611 5208

###### Email address

m\_sadeghi@crc.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Governmental

##### Expected recruitment start date

2017-01-20, 1395/11/01

##### Expected recruitment end date

2017-04-21, 1396/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effects of growth hormone (GH) on the results of echocardiography in patients with heart failure (HF) four weeks after myocardial infarction (MI)

##### Public title

The effects of growth hormone (GH) on the results of echocardiography in patients with heart failure (HF) four weeks after myocardial infarction (MI)

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Male; first-time MI; Ejection Fraction (EF) < 45% at discharge. Exclusion criteria: Patients with insulin-dependent diabetes mellitus (IDDM); Failure to control blood pressure (BP) in patients within 4 weeks after discharge from hospital; History of pulmonary disease other than asthma; Known chronic hepatic disease; Cr $\geq$ 2.5 or GFR $\leq$ 60; Systemic disease of all types; History of active infection or intake of antibiotics after discharge from hospital; HIV positive; Intake of corticosteroids within the last 4 weeks; Regularly intake

of alcohol within 4 weeks after discharge. 11. Any history or evidence from examination for malignant condition 12. Any history indicating malignant condition in patient or his/her first degree relatives 13. Any blood problems (even iron deficiency or anemia) 14. Any skeletal (bone) problems (except osteoporosis) 15. any history of peripheral vascular disease (PVD) 16. Any evidence of severe (Aortic) Valve Stenosis or heart valve failure 17. Any severe valve failure 18. Moderate and severe ventricular hypertrophy 19. Any type of heart block 20. Retinopathy for any reason 21. Any type of thyroid disorder

#### Age

From **40 years** old to **70 years** old

#### Gender

Male

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **32**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

### 1

#### Registry name

-

#### Secondary trial Id

-

#### Registration date

empty

### 2

#### Registry name

-

#### Secondary trial Id

-

#### Registration date

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Isfahan University of Medical

Sciences

#### Street address

Isfahan University of Medical Sciences, Hezarjereb Ave, Isfahan, Iran

#### City

Isfahan

#### Postal code

#### Approval date

2016-09-22, 1395/07/01

#### Ethics committee reference number

IR.MUI.REC.1395.8.74

## Health conditions studied

### 1

#### Description of health condition studied

Heart failure

#### ICD-10 code

I20-I25

#### ICD-10 code description

I24.8

## Primary outcomes

### 1

#### Description

Ejection Fraction (EF)

#### Timepoint

Immediately after injection, and three months later

#### Method of measurement

3-Dimensional Echocardiography

### 2

#### Description

Ventricular septum and left ventricular wall thickness

#### Timepoint

Immediately after injection, and three months later

#### Method of measurement

2-Dimensional Echocardiography

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: Receiving growth hormone a dose of 5 mg, every other day for 3 months through subcutaneous injection

#### Category

Treatment - Drugs

### 2

#### Description

Control group : Receiving placebo

**Category**  
Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Shahid Chamran Heart hospital

**Full name of responsible person**

Masoumeh Sadeghi MD

**Street address**

Moshtagh sevom Ave, Shahid Chamran Heart hospital

**City**

Isfahan

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, School of Medicine,  
Isfahan University of Medical Sciences

**Full name of responsible person**

Behzad Yavari MD

**Street address**

Isfahan

**City**

Isfahan

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellor for research, School of Medicine, Isfahan  
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**

Isfahan Cardiovascular Research Institute

**Full name of responsible person**

Masoumeh Sadeghi MD

**Position**

Professor of Cardiology

**Other areas of specialty/work**

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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)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*