

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Effect of metformin on diastolic heart failure in diabetic patient with diastolic heart failure

#### Protocol summary

##### Study aim

the effect of metformin on diastolic heart failure in diabetic patient with diastolic heart failure

##### Design

This is a double-blind, clinical interventional study. 114 patients with diabetes mellitus were enrolled in Amirmomenin Hospital.

##### Settings and conduct

This is a double-blind, clinical interventional study. 114 patients with diabetes mellitus were enrolled in Amirmomenin Hospital.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Not receiving metformin over the past 6 months, HbA1C less than 8/5, preserved EF or normal EF  
Exclusion criteria: Intolerance to metformin, DKA, GFR less than 30, systolic heart failure

##### Intervention groups

The first group of patients receiving metformin and the second group of patients who did not receive metformin. The first one received 500 milligram of metformin in the first week and we added 500 milligram to the patient's diet for a weekly period of two weeks. Daily dose of metformin for patients is 1500 milligram.

##### Main outcome variables

the effect of metformin on diastolic heart failure in diabetic patient with diastolic heart failure

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20141209020258N69**  
Registration date: **2018-02-20, 1396/12/01**  
Registration timing: **registered\_while\_recruiting**

Last update: **2018-02-20, 1396/12/01**

Update count: **0**

##### Registration date

2018-02-20, 1396/12/01

##### Registrant information

###### Name

Fariba Farokhi

###### Name of organization / entity

Arak University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3222 2003

###### Email address

f.farokhi@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-10-29, 1396/08/07

##### Expected recruitment end date

2019-10-29, 1398/08/07

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of metformin on diastolic heart failure in diabetic patient with diastolic heart failure

##### Public title

Effect of metformin on diastolic heart failure in diabetic patient with diastolic heart failure

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Not receiving metformin over the past 6 months HbA1C

less than 8/5 Preserved EFor normal EF

**Exclusion criteria:**

Intolerance to metformin DKA GFR less than 30 systolic heart failure

**Age**

From **30 years** old to **70 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **114**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization with random numbers

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The patient is not aware of the treatment received. Participant and Analyzer are blind (double blind).

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee Arak University Of Medical Sciences

**Street address**

Vice chancellor for research, Payambar azam complex, Basij square, Sardasht, Arak

**City**

Arak

**Province**

Markazi

**Postal code**

3814957558

**Approval date**

2017-10-29, 1396/08/07

**Ethics committee reference number**

IR.ARAK.MU.REC.1396.151

**Health conditions studied**

1

**Description of health condition studied**

Melitus diabetes

**ICD-10 code**

E08

**ICD-10 code description**

Diabetes mellitus due to underlying condition

**Primary outcomes**

1

**Description**

Determine the degree of diastolic failure

**Timepoint**

Initially and 4 months after starting treatment

**Method of measurement**

Ecocardiography

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group: The first group of patients receiving metformin .The first one received 500 milligram of metformin in the first week and we added 500 milligram to the patient's diet for a weekly period of two weeks. Daily dose of metformin for patients is 1500 milligram.

**Category**

Treatment - Drugs

2

**Description**

Control group: the second group of patients who did not receive metformin.

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Amiralmomenin hospital

**Full name of responsible person**

Dr Afsaneh Talaei

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Amiralmomenin hospital, Sardasht

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Dr Arjmandzadegan  
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Vice chancellor for research, Payambar azam complex, Basij square, Sardasht, Arak  
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arjmandzadegan@arakmua.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Arak 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**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Dr Alireza Alisaeeedi  
**Position**  
Assistant  
**Latest degree**  
Specialist  
**Other areas of specialty/work**

Cardiology  
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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Dr Afsaneh Talaee  
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Assistant  
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Subspecialist  
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Internal Medicine  
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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Dr Soheila Gholizadeh  
**Position**  
resident of internal  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

When we publish article in journal.

**When the data will become available and for how long**

After the article is published

**To whom data/document is available**

researcher in university

**Under which criteria data/document could be used**

If there are additional questions

**From where data/document is obtainable**

Dr afsaneh Talaee

**What processes are involved for a request to access data/document**

They have to write letters to the professors and the university.

**Comments**