

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Evaluation of urolithin A efficacy in heart failure patients with reduced ejection fraction

#### Protocol summary

##### Study aim

Evaluation of Urolithin A efficacy in alleviating symptoms of heart failure patients with reduced ejection fraction

##### Design

Placebo controlled, cross-over, randomized, triple-blinded phase 3 clinical trial on 10 participants. Randomization will be done using randomization.com website.

##### Settings and conduct

The study will be conducted in Specialized Cardiology Clinic. In cross-over study participants will receive 250 mg BID for 1 month. Washout period will be 2 weeks. Participants, clinician and statistician will be unaware of the assigned treatment.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: male, age between 25 and 85 years, Left ventricular ejection fraction (LVEF) equal or lower than 40%, New York Heart Association functional class equal or greater than II Exclusion criteria: history of myocardial infarction during the 8 past weeks, history of any malignant disease, renal failure, hepatic disorder

##### Intervention groups

Intervention group: In cross-over study participants will receive 250 mg BID for 1 month. Washout period will be 2 weeks. Control group: Participants will receive placebo tablets with similar appearance to intervention group. Tablets contain FDA accepted excipients.

##### Main outcome variables

LVEF

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210216050375N1**

Registration date: **2021-02-27, 1399/12/09**

Registration timing: **prospective**

Last update: **2021-02-27, 1399/12/09**

Update count: **0**

##### Registration date

2021-02-27, 1399/12/09

##### Registrant information

###### Name

Milad Iranshahy

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3180 1253

###### Email address

iranshahiml@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-08-23, 1400/06/01

##### Expected recruitment end date

2022-03-20, 1400/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of urolithin A efficacy in heart failure patients with reduced ejection fraction

##### Public title

Urolithin A in heart Failure

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Male Between the ages 25 to 85 years Left ventricular

ejection fraction equal or lower than 40% New York Heart Association functional class equal or greater than II Received standard treatment of heart failure (including Angiotensin-converting enzyme 2 inhibitors or Angiotensin II receptor inhibitors and beta blockers) for at least 2 weeks Signed informed consent

**Exclusion criteria:**

History of myocardial infarction during the 8 past weeks History of any malignant disease Renal failure (eGFR lower than 20 ml/1.73 m<sup>2</sup>/min) hepatic disorder (aminotransferase > 2x upper limit of normal) Extensive heart surgery or angioplasty during the past 30 days Allergy and/or hypersensitivity to specific drugs or substances related to drug used in this clinical trial uncontrolled high blood pressure (Systolic blood pressure higher than 180 mmHg and diastolic blood pressure higher than 100 mmHg)

**Age**

From **20 years** old to **85 years** old

**Gender**

Male

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **10**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization with random number tables using [www.randomization.com](http://www.randomization.com)

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

Participant, clinician and statisticians will be unaware of the assigned treatment

**Placebo**

Used

**Assignment**

Crossover

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

**Street address**

Azadi square, Mashhad University of Medical Sciences

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948954

**Approval date**

2021-02-13, 1399/11/25

**Ethics committee reference number**

IR.MUMS.REC.1399.629

**Health conditions studied**

**1**

**Description of health condition studied**

heart failure with reduced ejection fraction

**ICD-10 code**

I50

**ICD-10 code description**

Heart failure

**Primary outcomes**

**1**

**Description**

Left ventricular ejection fraction

**Timepoint**

Before and 1 month after intervention

**Method of measurement**

Echocardiography

**Secondary outcomes**

**1**

**Description**

N-terminal pro b-type natriuretic peptide (NTproBNP)

**Timepoint**

Before and 1 month after intervention

**Method of measurement**

Evaluation in serum by using a commercially available kit

**2**

**Description**

NYHA functional class

**Timepoint**

Before and 1 month after intervention

**Method of measurement**

Evaluation of symptoms by clinician

**3**

**Description**

serum cardiac troponin

**Timepoint**

Before and 1 month after intervention

**Method of measurement**

Evaluation in serum by using a commercially available kit

## Intervention groups

1

### Description

Intervention group: Patients will receive 250 mg Urolithin A BID for one month.

### Category

Treatment - Drugs

2

### Description

Control group: placebo pills BID for one month

### Category

Placebo

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Parsian clinic

#### Full name of responsible person

Mohammad Ali Ansari

#### Street address

West Razi Ave, Imam Reza Square

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Razavi Khorasan

#### Postal code

9137913316

#### Phone

+98 51 3853 9960

#### Email

amir\_saheb2000@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Mohsen Tafaghodi

#### Street address

Daneshgah Ave

#### City

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#### Province

Razavi Khorasan

#### Postal code

9138813944

#### Phone

+98 51 3854 1538

#### Email

tafaghodim@mums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

### Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

#### Full name of responsible person

Milad Iranshahi

#### Position

Assistant Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Medical Pharmacy

#### Street address

Vakil Abad Blvd, school of pharmacy, Mashhad University of Medical Sciences

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iranshahiml@mums.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Milad Iranshahi

#### Position

Assistant Professor

#### Latest degree

Ph.D.

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Milad Iranshahi  
**Position**  
Assistant Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Medical Pharmacy  
**Street address**  
Vakil Abad Blvd  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available