

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

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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 m²/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

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

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West Razi Ave, Imam Reza Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Milad Iranshahi

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Person responsible for updating data

Contact

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Full name of responsible person
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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