Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of Valeriana officinalis extract on echocardiographic, laboratory and clinical parameters in patients with heart failure with reduced ejection fraction

Protocol summary

Study aim
Investigating the effect of Valeriana officinalis extract on echocardiographic, laboratory and clinical parameters in patients with heart failure with reduced ejection fraction

Design
Phase 3 randomized Double-blinded placebo parallel clinical trial on 68 patients. Randomization using Randomaization.com

Settings and conduct
This randomized clinical trial at Ghaem Hospital (Mashhad) will enroll patients randomly assigned to receive either active drug or identical placebo (double-blinded design with unique patient codes). Evaluations occur at baseline and 3-month follow-up.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Age ≥18 years, Heart failure with systolic dysfunction, Informed consent. And Exclusion Criteria: NYHA Class IV heart failure, Renal impairment (GFR <20 mL/min/1.73m²), Liver dysfunction (LFT >3×ULN), Low BMI (≤18.5 kg/m²), Use of: warfarin/lithium/chemotherapy, Pregnancy, Major comorbidities, Serious adverse reactions, Drug intolerance, Withdrawal of consent

Intervention groups
Intervention group: Taking Hydroalcoholic extract of Valeriana officinalis L tablets daily along with standard treatments. Placebo group: Taking placebo tablets daily along with standard treatments

Main outcome variables
Echocardiographic parameters (LVEF, RV strain, PAP, RV diameter), laboratory parameters (CBC, CRP, Chol, TG, LDH, ALT, AST, uric acid), and the CHFQOLQ-20 questionnaire.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250405065212N1**
Registration date: **2025-04-19, 1404/01/30**
Registration timing: **prospective**

Last update: **2025-04-19, 1404/01/30**
Update count: **0**

Registration date
2025-04-19, 1404/01/30

Registrant information

Name
Parnian Salehi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 23 3223 9591

Email address
salehip4011@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-04-21, 1404/02/01

Expected recruitment end date
2025-07-23, 1404/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of Valeriana officinalis extract on

echocardiographic, laboratory and clinical parameters in patients with heart failure with reduced ejection fraction

Public title

Investigating the effect of Valeriana officinalis extract on echocardiographic, laboratory and clinical parameters in patients with heart failure with reduced ejection fraction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age ≥ 18 years Diagnosis of heart failure with systolic dysfunction Provision of informed consent for study participation

Exclusion criteria:

Class IV heart failure according to the New York Heart Association (NYHA) criteria History of renal dysfunction (GFR < 20 mL/min/1.73m²) History of hepatic dysfunction (LFT > 3 × ULN) Severe underweight (BMI ≤ 18.5 kg/m²) Use of warfarin, lithium, or chemotherapeutic agents Pregnancy or suspected pregnancy Other underlying conditions or comorbidities, including active infections, major surgeries, type 1 diabetes, pituitary or adrenal insufficiency, malnutrition, substance abuse or dependence, gastrointestinal disorders, or malignancy. Occurrence of a serious adverse event during the study (e.g., hypersensitivity reaction) Patient withdrawal of consent Unwillingness to continue participation

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Methodology for Random Sequence Generation with Software or Website Specification: Randomization was achieved using a random number table generated from the website www.randomization.com. In this study, a block randomization method was employed to generate a sequence of random numbers. This method utilized 20 blocks of size 4 and 20 blocks of size 2, randomly selected from combinations of letters A and B using the random number table. The list of blocks of size 2 includes: 1: AB and 2: BA. The list of blocks of size 4 includes: 1: AABB, 2: ABBA, 3: BBAA, 4: BAAB, 5: BABA, 6: ABAB. To select the blocks of size 2, 20 numbers were randomly chosen from the random number table. If the selected number ranged from 0 to 4, the first block was chosen; if the number ranged from 5 to 9, the second block was selected. For selecting the blocks of size 4, 20 numbers were randomly selected from the range of 1 to 6 using the random number table. If the selected number was one, the first block of size four was chosen; if the selected number was two, the second block was chosen, and this procedure continued for the remaining blocks. Allocation Concealment Methodology: The generated allocation sequence was placed in sealed envelopes and will be opened at the time of patient enrollment in the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding will performed using sealed envelopes. Due to the use of a placebo similar to the intervention treatment, the investigator and the participants will not be informed of the assigned treatment, and the analyst will also be unaware of the assigned treatment for the two groups Finally, after analyzing the data, the researcher who prepared the packages will reveal the codes A and B

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine-Mashhad University of Medical Sciences

Street address

School of Medicine, University pardis, Eastern Entrance at Azadi Square, Kalantari Highway, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2025-01-20, 1403/11/01

Ethics committee reference number

IR.MUMS.IRH.REC.1403.200

Health conditions studied

1

Description of health condition studied

Left ventricular failure

ICD-10 code

I50.1 - Le

ICD-10 code description

Left ventricular failure

Primary outcomes

1

Description
Echocardiographic parameters (LVEF, RV strain, PAP, RV diameter)
Timepoint
Before intervention and 3 month after intervention
Method of measurement
Echocardiography

Secondary outcomes

1

Description
laboratory parameters (CBC, CRP, Chol, TG, LDH, ALT, AST, uric acid)
Timepoint
Before intervention and 3 month after intervention
Method of measurement
measured from fasting venous blood using standardized automated analyzers

2

Description
CHFQOLQ-20(Congestive Heart Failure Quality of Life Questionnaire (20-item version)) questionnaire
Timepoint
Before intervention and 3 month after intervention
Method of measurement
Completion of questionnaires

Intervention groups

1

Description
Intervention group: Using tablet containing 400 mg of Valeriana officinalis hydroalcoholic extract administered once daily + standard heart failure therapy
Category
Treatment - Drugs

2

Description
Control group: Taking placebo tablets four times a day along with standard treatments
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Parnian Salehi
Street address
Mashhad, Ahmadabad Blvd
City
Mashhad
Province
Razavi Khorasan
Postal code
99199-91766
Phone
+98 51 3840 0001
Email
salehip4011@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen tafaghodi
Street address
Research Institutes, Mashhad University of Medical Sciences, daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9137914934
Phone
+98 51 3859 3242
Email
salehip4011@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
Parnian Salehi

Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Cardiology
Street address
Ahmadabad Blvd
City
Mashhad
Province
Razavi Khorasan
Postal code
99199-91766
Phone
+98 51 3840 0001
Email
salehip4011@mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Parnian Salehi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Cardiology
Street address
Ahmadabad Blvd
City
Mashhad
Province
Razavi Khorasan
Postal code
99199-91766
Phone
+98 23 3223 9591
Email
salehip4011@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Parnian Salehi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Cardiology
Street address
Ghaem Hospital, Ahmadabad Blvd
City
Mashhad
Province
Razavi Khorasan
Postal code
99199-91766
Phone
+98 23 3223 9591
Email
salehip4011@mums.ac.ir

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