

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of Colchicin effects on the quality of life and clinical evidence in patients with acute Decompensated heart failure

#### Protocol summary

##### Study aim

Determining the effect of colchicine on quality of life in patients with acute heart failure referred to Bu Ali Hospital

##### Design

This clinical trial has 2 intervention groups, Three-blinded, 70 acute heart failure patients are randomly divided into two groups using the random assignment rule. Each of these selected individuals will be assigned a numerical sequence from 1 to 70. Then, using the Statistics and Sample Size software, the random sequence will be considered for entering individuals into the study.

##### Settings and conduct

Patients aged 18-80 who referred to Bu-Ali-Sina Hospital in Qazvin in 2025 with acute heart failure are studied. Demographic information is recorded on the first day of hospitalization. Anti-inflammatory treatment is given in the emergency room and then in a maintenance dose for 8 weeks in one group with Colchicine and in the other group with placebo.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: acute heart failure evidence of congestion 18 and 80 years Exclusion criteria: Incomplete records and questionnaire Neuromyosarcoma, hematological, rheumatic, severe gastrointestinal disease, peptic ulcer, chronic diarrhea, malabsorption, cirrhosis or chronic liver disease and COPD Severe and recurrent arrhythmia currently taking colchicine Severe valvular heart disease GFR < 30 allergy to colchicine using immunosuppressive drugs, steroids or IL1 antagonists pregnancy and breastfeeding Non-cooperation Life expectancy less than 6 months

##### Intervention groups

An initial dose of 2 mg of colchicine (manufactured by Darou Pakhsh Company, Tehran, Iran) is given at the time of emergency admission, followed by a maintenance dose of 0.5 mg twice daily for 8 weeks. For patients older than 75 years, weighing less than 70 kg,

and with a GFR less than 50, the dose is reduced to 1.5 mg as a maintenance dose and 0.5 mg daily for 8 weeks.

##### Main outcome variables

Quality of life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20250421065417N1**

Registration date: **2025-05-25, 1404/03/04**

Registration timing: **registered\_while\_recruiting**

Last update: **2025-05-25, 1404/03/04**

Update count: **0**

##### Registration date

2025-05-25, 1404/03/04

##### Registrant information

##### Name

Elahe Motamedi rad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 990 740 8784

##### Email address

mojtaba.shakeri212@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2025-05-10, 1404/02/20

##### Expected recruitment end date

2025-08-21, 1404/05/30

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of Colchicin effects on the quality of life and clinical evidence in patients with acute Decompensated heart failure

**Public title**

Evaluation the effect of Colchicine on quality of life in patients with acute heart failure

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Acute heart failure based on signs and symptoms and echo in the emergency room Presence of clinical and radiological evidence of congestion

**Exclusion criteria:**

Inflammatory bowel disease, chronic diarrhea, or malabsorption disease severe gastrointestinal illness  
Peptic ulcer Rheumatic inflammatory disease  
Neuromuscular disease Hematological disease Severe and recurrent arrhythmia Cirrhosis or active, chronic liver disease Patients currently taking Colchicine for another indication Severe valvular heart disease COPD GFR < 30  
Hypersensitivity to colchicine Chronic treatment with Immunosuppressive drugs, steroids, or IL1 antagonists  
Pregnancy or breastfeeding Life expectancy less than 6 months

**Age**

From **18 years** old to **80 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

To implement random allocation, creating a random sequence using the "Random Allocation Law" method will be used. Thus, after determining the sample size, among the people identified in the first stage, several people who meet the criteria for entering the study, are willing to participate in the study and sign the informed consent form, will be selected using the accessible method. In the second stage, each of these selected people will be assigned a numerical order from 1 to 70. In the third step, 70 random sequences created by Statistics and Sample Size software (random numbers without repetition between 1 and 70) will be considered to

include people in the study. Each of these numbers will correspond to the number assigned to a person, which is specified in the first list of 70. The numbers will be assigned to the intervention group (prescribing Colchicine) and the control group in sequence, and this sequence will be repeated to obtain the desired number of samples for each group. How the random assignment will be performed and to which group the individual will be specialized will not be obvious to the participants.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

Doctors and researchers collecting data and investigating the outcome and health care personnel will be unaware of the intervention groups. Colchicine and Placebo drugs have been prepared and will be placed in the hospital without its medicinal properties. Medication packages are prepared by a separate pharmacist. A special code for the type of drug is specified on each package, which identifies it in the study database.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Qazvin University of Medical Sciences

**Street address**

Qazvin University of Medical Sciences, Shahid Bahonar Boulevard

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3419759811

**Approval date**

2025-04-20, 1404/01/31

**Ethics committee reference number**

IR.QUMS.REC.1404.013

**Health conditions studied****1****Description of health condition studied**

Acute decompensated heart failure

**ICD-10 code**

I50.21

**ICD-10 code description**

Acute systolic (congestive) heart failure

## Primary outcomes

1

### Description

The quality of life

### Timepoint

Upon discharge - two months after discharge

### Method of measurement

McNew Quality of Life Questionnaire

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: Initial dose (loading) of 2 mg of colchicine (manufactured by Darou Pakhsh Company, Tehran, Iran) is received at the time of emergency admission and then a maintenance dose of 0.5 mg twice daily for 8 weeks. For patients older than 75 years, weighing less than 70 kg, and GFR less than 50, the dose is reduced and colchicine is prescribed as a maintenance dose of 1.5 mg and 0.5 mg daily for 8 weeks.

### Category

Treatment - Drugs

2

### Description

Control group: They receive a placebo (with lactose) pill at the time of emergency room visit and then twice a day for 8 weeks.

### Category

Placebo

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

BouAli Sina Hospital

#### Full name of responsible person

Elahe Motamedi

#### Street address

Bouali Hospital, Bouali Street

#### City

Qazvin

#### Province

Qazvin

#### Postal code

3413786165

#### Phone

+98 28 3332 6034

#### Email

motamedielae972@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Qazvin University of Medical Sciences

#### Full name of responsible person

Seyed Mahdi Mirhashemi

#### Street address

Vice-Chancellor's Office for Research and Technology Affairs, Qazvin University of Medical Sciences, Shahid Beheshti Avenue

#### City

Qazvin

#### Province

Qazvin

#### Postal code

34199-15315

#### Phone

+98 28 3333 7006

#### Email

sm.mirhashemi@qums.ac.ir

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

#### Full name of responsible person

Elahe Motamedi

#### Position

resident

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Cardiology

#### Street address

Bouali Hospital, Bouali Street

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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**Latest degree**

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**Province**

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**Postal code**

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**Phone**

+98 28 3332 6032

**Email**

motamedielaha972@gmail.com

## 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**

Undecided - It is not yet known if there will be 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**

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

**Data Dictionary**

No - There is not a plan to make this available

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

All data is potentially shareable after unidentified individuals

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

Access period starts 6 months after the results are published

**To whom data/document is available**

Access period starts 6 months after the results are published

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

Academic and scientific researchers and Industries

**From where data/document is obtainable**

Submit request via email motamedielaha971@gmail.com

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

If the applicant submits a request, if 6 months have passed since the publication of the article, it will be answered in less than 1 week.

**Comments**