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 beastfeeding 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

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Elahe Motamedi rad
Name of organization / entity
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Iran (Islamic Republic of)
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+98 990 740 8784
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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
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3413786165
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motamedielahe972@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
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Qazvin
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34199-15315
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+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
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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
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 motamedielahe971@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