

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Evaluation of quality of life in patients with heart failure treated with colchicine

Protocol summary

Study aim

Evaluation of quality of life in patients with heart failure treated with colchicine

Design

Clinical trial with control group, with parallel groups, uncorrected, randomized, phase 2_3 on 60 patients

Settings and conduct

This is a prospective , randomized controlled trial on a total 60 consented of patients with heart failure in the age group over 18 years and under 80 years who have filled out the informed consent form. And to treat their heart failure , they have referred to the clinic of Shahid Madani Research and Treatment Center in Tabriz .In addition to routine treatment ,patients in the intervention group will also receive 0.5 mg twice daily colchicine. Examination of inflammatory femurs will be three times (before starting treatment with colchicine and one month later and three months later).

Participants/Inclusion and exclusion criteria

The condition for entering this research project include these items ;Patients with heart failure which completed the consent form. The condition for not entering this research project are as follow ; Patients with heart failure with colchicine allergy and patients with heart failure who have not completed the consent form.

Intervention groups

Intervention group will receive in addition to routine treatment,0.5 mg twice a day of colchicine. Patient in the control group will receive only routine treatment.

Main outcome variables

Evaluation of changes in serum levels of inflammatory factors in heart failure and change in quality of life in patients with heart failure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111206008307N38**

Registration date: **2022-04-09, 1401/01/20**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-09, 1401/01/20**

Update count: **0**

Registration date

2022-04-09, 1401/01/20

Registrant information

Name

Taher Entezari-Maleki

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6695 4709

Email address

tentezarimaleki@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-06-21, 1401/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of quality of life in patients with heart failure treated with colchicine

Public title

Evaluation of quality of life in patients with heart disease being treated with colchicine

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with heart failure Patients with a history of cardiac ischemia Patients with a history of thromboembolism Patients with high serum levels of inflammatory factors in heart failure and cardiovascular problems Patients with less renal glomerular filtration rate 30mm Hg /min/1.73 m² Patients with symptomatic hypotension and systolic pressure below 100 or above 180 mm Hg Complete the consent form

Exclusion criteria:

Patients with heart failure who are treated on an outpatient basis and do not need to be hospitalized Patients with heart failure are in the age group under 18 years and over 80 years Patients with heart failure with colchicine allergy Patients with heart failure who have not completed the consent form

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **3**

Patients will be sampled by more than one sample per patient and the sample size will be pilot.

Randomization (investigator's opinion)

Randomized

Randomization description

Given that the number of cases in this research project is 60 people which should be randomly divided into two groups of 30 people ,so; How to randomize in this research project will be done as follow which patients will be divided into two groups of 30 by systematic randomization and computer generated numbers .

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Tabriz University of Medical Scienc

Street address

Research and Technology Deputy, Tabriz University of Medical Science,Golgasht Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2022-02-09, 1400/11/20

Ethics committee reference number

IR.TBZMED.REC.1400.1132

Health conditions studied

1

Description of health condition studied

Patients with heart failure

ICD-10 code

I50

ICD-10 code description

Heart failure

Primary outcomes

1

Description

Changes in the quality of life of heart failure patients with administration of the drug

Timepoint

Evaluation and determination of quality of life in patients with heart failure at the beginning of the study (before the intervention), 30 days and 90 days after the intervention

Method of measurement

Using the completion of the KCCQ questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group includes patients with heart failure who in addition to standard treatment will also take 0.5 mg twice a day colchicine tablet for three months.

Category

Treatment - Drugs

2

Description

Control group: The control group includes patients with

heart failure who will receive only the standard treatment of heart failure.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Heart Center of Tabri

Full name of responsible person

Dr.Taher Entezari-Maleki

Street address

Shahid Madani Heart Center, Daneshghah Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3337 3901

Email

tentezari@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Mohammad Reza Rashidi

Street address

Daneshghah Street, Golgasht Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

335710

Phone

+98 41 3335 7310

Email

tentezari@gmail.com

Web page address

<http://researchvice.tbzmed.ac.ir>

Grant name

Grant code / Reference number

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

No

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Taher Entezari-Maleki

Position

Assistant professor/ Clinical Pharmacist

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Daneshghah street

City

Tabriz

Province

East Azarbaijan

Postal code

0098 41 33344798

Phone

+98 41 1339 2593

Fax

+98 41 1334 4798

Email

tentezari@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Taher Entezari-Maleki

Position

Assistant professor/Clinical Pharmacist

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of pharmacy , Daneshghah Street

City

Tabriz

Province

East Azarbaijan

Postal code

0098 41 33344798

Phone

+98 41 1339 2593

Email

tentezari@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Taher Entezari-Maleki

Position

Assistant professor/ Clinical Pharmacist

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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

Yes - There is 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

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All of the data of an article can be published after making patients unrecognized

When the data will become available and for how long

After publishing of article until 6 months after publishing of the results

To whom data/document is available

Data will be available to researchers working in academic and scientific institution

Under which criteria data/document could be used

Researchers that request data will be permitted only to doing analysis according to ethics for scientific aims

From where data/document is obtainable

Applicants can receive data by sending an E-mail to address of tentezari@gmail.com and get response from Dr.Taher Entezari-Maleki

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

After contacting with corresponding author(Dr.Taher Entezari-Maleki) , data will be sent to Tabriz Shahid Madani hospital ethics committee and after receiving permission data will be send to applicants .

Comments