

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Clinical trial of the effect of “Biebersteinia Multifida root” on quality of life in patients with systolic heart failure

Protocol summary

Study aim

Evaluation of the effect of Biebersteinia Multifida root extract on quality of life in patients with systolic heart failure

Design

This study is a randomized, double-blind clinical trial with parallel groups in which 60 patients are randomly divided into two case-control groups

Settings and conduct

Sixty patients with systolic heart failure were selected in the special cardiovascular clinic of Zanjan University of Medical Sciences and randomly divided into two equal groups of 30 people. Patients in the intervention and control groups receive 250 mg of Biebersteinia Multifida root extract and placebo per capsule every 12 hours, respectively. During the study, patients are examined every two weeks. Participants and researcher are blind and not a blind statistic consultant

Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent to participate in the study, Age 40 to 75, Systolic heart failure with ejection fraction equal or lesser than 40 percent, Continuing heart medications prescribed by cardiologist. Exclusion criteria: Pregnancy, Breast feeding, Malignancy, Allergy to Biebersteinia Multifida root extract, Unwillingness of the patient to continue cooperation, Chronic inflammatory disease, Severe renal failure, Collagen vascular disease, Severe liver disease, Acute infectious disease, Decompensated heart failure

Intervention groups

Biebersteinia Multifida root extract: Each patient in the intervention group takes a capsule for two months and every twelve hours Placebo: Each patient in the intervention group takes a capsule for two months and every 12 hours

Main outcome variables

Quality of life score in the Minnesota Questionnaire; The distance traveled in six minute walk test.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180130038565N1**

Registration date: **2018-02-19, 1396/11/30**

Registration timing: **prospective**

Last update: **2018-02-19, 1396/11/30**

Update count: **0**

Registration date

2018-02-19, 1396/11/30

Registrant information

Name

Ebadollah salekmoghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3313 1559

Email address

salekmoghadam@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-01, 1396/12/10

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of “Biebersteinia Multifida root” on quality of life in patients with systolic heart failure

Public title

Biebersteinia Multifida root in systolic heart failure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent to participate in the study Age 40 to 75 Systolic heart failure with ejection fraction equal or lesser than 40 percent Continuing heart medications, prescribed by cardiologist

Exclusion criteria:

Pregnancy Breast feeding Malignancy Allergy to Biebersteinia Multifida root extract Unwillingness of the patient to continue cooperation Chronic inflammatory disease Severe renal failure Collagen vascular disease Severe liver disease Acute infectious disease Decompensated heart failure

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

By using random numbers table, patients are divided in two 30 person case-control groups

Blinding (investigator's opinion)

Double blinded

Blinding description

All participants and researchers are blind in this study ,coding of medicine and placebo are under the responsibility of a statistical adviser who is not blind

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical

Sciences

Street address

Ethics committee, Zanjan University of Medical Sciences, Azadi sq., Jomhuri Islami Ave.

City

Zanjan

Province

Zanjan

Postal code

4515613191

Approval date

2018-01-23, 1396/11/03

Ethics committee reference number

IR.ZUMS.REC.1396.273

Health conditions studied

1

Description of health condition studied

Systolic heart failure

ICD-10 code

I50.2

ICD-10 code description

Systolic (congestive) heart failure

Primary outcomes

1

Description

Quality of Life Score in the Minnesota Questionnaire

Timepoint

Measure the quality of life score at the beginning of study (before intervention) and one week after taking the Biebersteinia Multifida root extract.

Method of measurement

Minnesota Living With Heart Failure Questionnaire

2

Description

The distance traveled in six minute walk test

Timepoint

Measure the distance traveled in six minute walk test at the beginning of study (before intervention) and one week after taking the Biebersteinia Multifida root extract

Method of measurement

Six minute walk test

Secondary outcomes

1

Description

Left ventricular ejection fraction

Timepoint

Measurement of left ventricular ejection fraction at the beginning of study (before intervention)

Method of measurement

Echocardiography

2

Description

Complete blood count

Timepoint

Measurement of complete blood count at the beginning of study (before intervention) and one week after taking the Biebersteinia Multifida Root Extract

Method of measurement

Blood test

3

Description

Blood urea nitrogen

Timepoint

Measurement of blood urea nitrogen at the beginning of study (before intervention) and one week after taking the Biebersteinia Multifida Root Extract

Method of measurement

Blood test

4

Description

Serum creatinine

Timepoint

Measurement of serum creatinine at the beginning of study (before intervention) and one week after taking the Biebersteinia Multifida Root Extract

Method of measurement

Blood test

5

Description

Alanine aminotransferase

Timepoint

Measurement of Alanine aminotransferase at the beginning of study (before intervention) and one week after taking the Biebersteinia Multifida Root Extract

Method of measurement

Blood test

6

Description

Aspartate aminotransferase

Timepoint

Measurement of Aspartate aminotransferase at the beginning of study (before intervention) and one week after taking the Biebersteinia Multifida Root Extract

Method of measurement

Blood test

7

Description

Alkaline phosphatase

Timepoint

Measurement of Alkaline phosphatase at the beginning of study (before intervention) and one week after taking the Biebersteinia Multifida Root Extract

Method of measurement

Blood test

8

Description

C-reactive protein

Timepoint

Measurement of C-reactive protein at the beginning of study (before intervention) and one week after taking the Biebersteinia Multifida Root Extract

Method of measurement

Blood test

Intervention groups

1

Description

Intervention group: Dry extract of Biebersteinia Multifida root with a concentration of 10 percent relative to 100 g of roots of the plant, has been standardized 250 mg per capsule at the school of Pharmacy of Shahid Beheshti University of Medical Sciences. The drug is given one capsule every 12 hours for 60 days to volunteer patients with systolic heart failure who have ejection fraction equal to or less than 40 percent.

Category

Treatment - Drugs

2

Description

Control group: Placebo in the control group contains starch corn which is provided in capsules and boxes of the same intervention group at the school of Pharmacy of Shahid Beheshti University of Medical Sciences. The placebo is given one capsule every 12 hours for 60 days to volunteer patients with heart failure who have ejection fraction equal to or less than 40 percent.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Special clinic of cardiovascular diseases of Zanjan University of Medical Sciences

Full name of responsible person

Ebadollah Salekmoghadam

Street address

Special clinic of cardiovascular disease of Zanjan University of Medical Sciences, Amin doctors' building, Haft tir st.

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Alireza Shoghli

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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

Zanjan 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**

Zanjan University of Medical Sciences

Full name of responsible person

Ebadollah Salekmoghadam

Position

Ph.D student of Iranian Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Hassan Ahangar

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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Person responsible for updating data

Contact**Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Ebadollah Salekmoghadam

Position

Ph.D student of Iranian Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

Education and Treatment Center of Valiasr, Valiasr sq.

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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