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., Jomhouri 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
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Full name of responsible person
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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