Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Clinical Trial of the Centaurea behen Root Effect on Quality of Life in Patients with Systolic Heart Failure

Protocol summary

Study aim
The aim of this study is assessment of effect of Centaurea behen root extract on quality of life of patients with Systolic Heart Failure.

Design
This study is a randomized double-blind clinical trial with parallel groups. Using random number table, 60 patients are divided into two intervention and control groups.

Settings and conduct
Sixty selected patients with systolic heart failure in Cardiovascular Clinic of Zanjan University of Medical Sciences are randomly divided into two groups of 30 patients. Patients of intervention group take a 150 milligrams capsule of Centaurea behen root extract, every 12 hours for 60 days and patients of placebo group take a capsule of placebo contains corn starch, every 12 hours for 60 days. During the study, patients are examined every two weeks. Participants and researcher are blind, and statistical adviser is not blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Informed study participation, Age 40 to 75, Systolic heart failure with ejection fraction equal or lesser than 40 percent, Currently taking heart medications prescribed by cardiologist. Exclusion criteria: Pregnancy, Breast feeding, Allergy to Centaurea behen root extract, Patient's unwillingness to continue participation, Chronic inflammatory disease, Severe renal failure, Collagen vascular disease, Severe liver disease, Acute infectious disease, Malignancy, Decompensated heart failure.

Intervention groups
Centaurea behen root extract: Each patient in the intervention group takes a capsule for two months and every 12 hours. Placebo: Each patient in the control 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 The Six Minute Walk Test.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180130038563N1**
Registration date: **2018-02-21, 1396/12/02**
Registration timing: **prospective**

Last update: **2018-02-21, 1396/12/02**
Update count: **0**

Registration date
2018-02-21, 1396/12/02

Registrant information
Name
Saeid Yousefi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 24 3377 0801
Email address
sayusefi@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 Centaurea behen Root Effect on Quality of Life in Patients with Systolic Heart Failure

Public title
Effect of Centaurea behen Root in Systolic Heart Failure
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Informed study participation Age 40 to 75 Systolic heart failure with ejection fraction equal or lesser than 40 percent Currently taking heart medications, prescribed by cardiologist
Exclusion criteria:
Pregnancy Breast feeding Allergy to Centaurea behen root extract Patient's unwillingness to continue participation Chronic inflammatory disease Severe renal failure Collagen vascular disease Severe liver disease Acute infectious disease Malignancy 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 number table, patients are divided into two 30 patients intervention-control groups
Blinding (investigator's opinion)
Double blinded
Blinding description
All participants and researcher are blind in this study, coding of drug and placebo are under the responsibility of the 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 Univerisity 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.1396.272

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
The Quality of Life Score in the Minnesota Questionnaire
Timepoint
At the beginning of the study (before intervention) and one week after the end of the Centaurea behen Root Extract taking
Method of measurement
The Minnesota Living with Heart Failure Questionnaire

2

Description
The Distance traveled in The Six Minute Walk Test
Timepoint
At the beginning of the study (before intervention) and one week after the end of the Centaurea behen Root Extract taking
Method of measurement
The Six Minute Walk Test

Secondary outcomes

1

Description
The Left Ventricular Ejection Fraction
Timepoint
At the beginning of the study (before intervention)
Method of measurement
Echocardiography

2

Description
Complete blood count
Timepoint
At the beginning of the study (before intervention) and one week after the end of the Centaurea behen Root Extract taking
Method of measurement
Blood test

3

Description
Blood urea nitrogen
Timepoint
At the beginning of the study (before intervention) and one week after the end of the Centaurea behen Root Extract taking
Method of measurement
Blood test

4

Description
C-reactive protein
Timepoint
At the beginning of the study (before intervention) and one week after the end of the Centaurea behen Root Extract taking
Method of measurement
Blood test

5

Description
Serum creatinine
Timepoint
At the beginning of the study (before intervention) and one week after the end of the Centaurea behen Root Extract taking
Method of measurement
Blood test

6

Description
Aspartate aminotransferase
Timepoint
At the beginning of the study (before intervention) and one week after the end of the Centaurea behen Root Extract taking
Method of measurement
Blood test

7

Description
Alanine aminotransferase
Timepoint
At the beginning of the study (before intervention) and one week after the end of the Centaurea behen Root Extract taking
Method of measurement
Blood test

8

Description
Alkaline phosphatase
Timepoint
At the beginning of the study (before intervention) and one week after the end of the Centaurea behen Root Extract taking
Method of measurement
Blood test

Intervention groups

1

Description
Intervention group: A Centaurea behen root extract, with a concentration of 20 percent from plant root and as capsules with a dose of 150 milligrams of dried extract that has been standardized based on total phenol, has been made in the Pharmacognosy Department of the Faculty of Pharmacy, Shahid Beheshti University of Medical Sciences. With two-way blindness being observed, the 30 patients in the intervention group, are given a capsule for two months and every 12 hours.
Category
Treatment - Drugs

2

Description
Control group: The placebo used in this study is made of corn starch and in terms of its appearance and type of packaging, it is similar to the main drug. It has been made in Pharmacognosy department of Faculty of Pharmacy, Shahid Beheshti University of Medical Sciences. With two-way blindness being observed, the 30 patients, In the control group, are given a capsule for two months and every 12 hours.
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
Saeid Yousefi
Street address
Special Clinic of Cardiovascular Diseases of Zanjan University of Medical Sciences, Amin Doctor's Building, Haft Tir st.
City
Zanjan
Province
Zanjan

Postal code
4518617384
Phone
+98 24 3356 5333
Email
ahanghar@zums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Alireza Shoghli
Street address
Deputy of Research and Technology, Zanjan Univerisity of Medical Sciences, Azadi sq., Jomhouri Islami Ave.
City
Zanjan
Province
Zanjan
Postal code
4515613191
Phone
+98 24 3342 0677
Fax
+98 24 3342 4770
Email
shoghli@zums.ac.ir
Web page address
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
Saeid Yousefi
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.
City
Zanjan
Province
Zanjan
Postal code
4515777978
Phone
+98 24 3377 0801
Fax
+98 24 3377 0757
Email
sayusefi@zums.ac.ir

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
Street address
Special Clinic of Cardiovascular Diseases of Zanjan University of Medical Sciences, Amin Doctor's Building, Haft Tir st.
City
Zanjan
Province
Zanjan
Postal code
4518617384
Phone
+98 24 3356 5333
Email
ahanghar@zums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Saeid Yousefi
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.

City
Zanjan
Province
Zanjan
Postal code
4515777978
Phone
+98 24 3377 0801
Email
sayusefi@zums.ac.ir

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