Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Clinical trial of the effect of "Rheum palmatum root"on quality of life in patients with systolic heart failure

Protocol summary

Study aim

The Rheum palmatum effect on patients with systolic heart failure. Recuperate patients with systolic heart failure after taking Rheum palmatum.

Design

By using random numbers table, patios are divided in two person case-control groups 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.

Settings and conduct

Intervention group:Dry extract of Rheum palmatum root with a concentration of 10% relative to 100 of roots of the plant, has been standardized 250mg per capsule.the drug is given one capsule every 12 hours for 60 days to volunteer patients with heart failure who have ejection fraction equal to or less than40%(the patients refer to special clinic Zanjan university of Medical science) Control group:Placebo in the control group contains starch corn which is provided in capsules and boxes of the same intervention group.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%(the patients refer to special clinic Zanjan university of Medical science) All participations and researchers are blind in this study, coding of medicine and placebo are under the responsibility of a statistical adviser who isnot blind.

Participants/Inclusion and exclusion criteria

Informed study participation, age 40 to 75, systolic heart failure with ejection fraction equal or lesser than 40 percent, continuing heart medications, prescribed by cardiologist Pregnancy, Breast feeding, malignancy, Allergy to Rheum palmatum root extract, unwillingness of the patient to continue cooperation, chronic inflammatory disease, severe liver disease, Acute infectious disease, Decompensation heart failure

Intervention groups

60 Patients have systolic heart failure at 40 to 75 years that conditions have in plan.30 person take placebo and 30 person take drug

Main outcome variables

1-Quality of life score in the Minnie so ta Questionnaire before and after intervention 2-The distance traveled in six minute walk test before and after intervention 3-Left ventricular ejection fraction before and after intervention 4-Complete blood count, Ast-Alt, Bun-Cr, CRP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180206038645N1**
Registration date: **2018-03-05, 1396/12/14**
Registration timing: **prospective**

Last update: **2018-03-05, 1396/12/14**
Update count: **0**

Registration date

2018-03-05, 1396/12/14

Registrant information

Name

Zohre Gholami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3377 0801

Email address

gholami1393@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-04, 1397/01/15

Expected recruitment end date
2018-06-05, 1397/03/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical trial of the effect of "Rheum palmatum root"on quality of life in patients with systolic heart failure

Public title
Rheum palmatum 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 Continuing heart medications prescribed by cardiologist
Exclusion criteria:
Pregnancy Breast feeding Malignancy Hypersensivity to rheum palmatum root Unwillingness of the patient to continue coperation Chronic Inflamatory diseas Severe Renal failure Collagen vascular disease Sever liver disease Acute infectious disease De compensated 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 patiends are divided in two 30 person case_control groups
Blinding (investigator's opinion)
Triple blinded
Blinding description
All participations 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 San Jan University of Medical Sciences, A said Sq, Josh our Islamic Ave
City
Zanjan
Province
Zanjan
Postal code
4515777978
Approval date
2018-01-23, 1396/11/03
Ethics committee reference number
IR.Zums.REC.1396.271

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 Rheum Palmatum 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 beagining of study(before intervention)and one week after taking the Rheum Palmatum 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
Ecocardiography

2

Description
Complete blood count
Timepoint
Measurement of complete blood count at the begining of study(before intervention)and one week after taking Rheum Palmatum Root Extract
Method of measurement
Blood test

3

Description
Cr
Timepoint
Measurement of creatinine at the beginning of study (be a for intervention) and one week after taking Rheum palmatum root extract
Method of measurement
Blood test

4

Description
ALT
Timepoint
Measurement of Alanin Aminotransfers at the beginning of first study (be a for intervention) and one week after taking Rheum palmatum root extract
Method of measurement
Blood test

5

Description
AST
Timepoint
Measurement of Aspartat Aminotransferas at the begining first study (be a for intervention) and one week after taking Rheum palmatum root extract.
Method of measurement
Blood test

6

Description
CRP
Timepoint
Measurement of C_Reactive Protein at the beginning of first study (be a for intervention) and one week after taking Rheum palmatum extract
Method of measurement
Blood test

7

Description
ALKP
Timepoint
Measurement of Alkaline phosphatas at the beginning of study (be a for intervention) and one week after taking Rheum palmatum extract.
Method of measurement
Blood test

Intervention groups

1

Description
Intervention group: Dry extract of Rheum palmatum root with a concentration of 10% relative to 100 gr of roots of the plant, has been standardized 250mg per capsule at the school of pharmacy of Shahid Behest university of Medical Sciences.The drug 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%
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 Behest 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 than40%
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Special Clinic in Zanjan University of Medical Sciences
Full name of responsible person
Zohre Gholami
Street address
7Tired St.
City
Zanjan
Province
Zanjan
Postal code
4515777978
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, San Jan University of Medical Sciences, Azadi Sq, Jomhour Islami Ave.Zanjan I
City
Zanjan
Province
Zanjan
Postal code
45154
Phone
+98 24 3342 0677
Fax
+98 24 3342 4770
Email
shoghli@zums.ac.ir
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
Zohre Gholami
Position
Ph.D student of Iranian Medicin
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address
Education and Treatment Center of ValiaSr, ValiaSr Sq. Zanjan
City
Zanjan
Province
Zanjan
Postal code
4515777978
Phone
+98 24 3377 0801
Fax
+98 24 3377 0757
Email
gholami1393@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 in zanjan university of Medical Sciences
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
Zohre Gholami
Position
Ph.D student Iranian medicin
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address
Education and Treatment Center of ValiaSr, valiaSr Sq zanjan
City
Zanjan
Province
Zanjan
Postal code

4515777978

Phone

+98 24 3377 0801

Email

gholami1393@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