

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, patients 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 than 40% (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 is not 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 Hypersensitivity to rheum palmatum root Unwillingness of the patient to continue cooperation Chronic Inflammatory diseases 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 patients 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 beginning 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 beginning 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 (before 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 (before 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 beginning first study (before 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 (before 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 (before 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 than 40%

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Special Clinic in Zanzan University of Medical Sciences

Full name of responsible person

Zohre Gholami

Street address

7Tired St.

City

Zanzan

Province

Zanzan

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