Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Evaluation the efficacy of “Aloe Vera” oral gel on the quality of life in patients with systolic heart failure : A double blind, randomized controlled trial

Protocol summary

Study aim

Evaluation the efficacy of “Aloe Vera” oral gel on the quality of life in patients with systolic heart failure

Design

A concealed, randomized, parallel group trial with blinded outcome assessment of 26 patients.

Settings and conduct

Aloe Vera gel or placebo is given one capsule in the same condition every 12 hours for 8 weeks to the systolic heart failure patients referred to the Yazd Cardiovascular Research Center. The participants will be allocated into two groups of intervention (Aloe Vera) and control (placebo) with titles A and B by using block randomization method. Participants, researcher, person who gives drug and investigators will be blinded to all study. Only the randomization statistician will be unblinded to the treatment assignment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Written informed consent, age:18 years or above, systolic heart failure with ejection fraction equal or lesser than 40 percent or Heart failure with NYHA Class II-III, continuing heart medications, prescribed by cardiologist, Heart failure stable according to the diagnosis and under the supervision of a heart specialist. Exclusion criteria: Pregnancy, Breast feeding, malignancy, Allergy to Aloe Vera gel, chronic inflammatory disease, severe liver disease, Acute infectious disease, Decompensation heart, History of peptic ulcer and hemorrhoid.

Intervention groups

Participants will be given interventions two times a day for next 8 weeks. Each capsule contains 150 mg of Aloe Vera gel or 150 mg starch in the same shape, color and cans.

Main outcome variables

Minnesota Living with Heart Failure Questionnaire Score (MLHFQ) The distance covered during a Six-Minute Walk Test (6 MWT) Insomnia Severity Index questionnaires score (ISI) Pittsburgh Sleep Quality Index questionnaires score (PSQI) STOP-BANG sleep apnea questionnaires score

General information

Reason for update

There were two modifications to the inclusion criteria: Age: 18 years or above Systolic heart failure disease with reduced left ventricular ejection fraction ≤40% or Symptomatic chronic heart failure NYHA class II-III.

Acronym

IRCT registration information

IRCT registration number: **IRCT20190803044426N1**
Registration date: **2019-12-25, 1398/10/04**
Registration timing: **registered_while_recruiting**

Last update: **2021-06-27, 1400/04/06**
Update count: **2**

Registration date

2019-12-25, 1398/10/04

Registrant information

Name
Saeideh Sabbaghzadegan
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-11, 1398/09/20

Expected recruitment end date

2020-03-10, 1398/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the efficacy of “Aloe Vera” oral gel on the quality of life in patients with systolic heart failure : A double blind, randomized controlled trial

Public title

Efficacy of Aloe Vera gel in systolic heart failure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Written informed consent Age: 18 years or above Systolic heart failure disease with reduced left ventricular ejection fraction ≤40% or Symptomatic chronic heart failure NYHA class II-III. Patients willing to continue their standard continuing heart medications which prescribed by cardiologist Ambulatory systolic heart failure patients in stable condition (no hospitalization during the trial and no planned surgery)

Exclusion criteria:

Pregnancy Breast feeding Hypersensitivity to Aloe Vera Chronic Inflammatory disease Collagen vascular disease History of peptic ulcer Acute infectious disease Decompensated heart failure Chronic liver disease Chronic renal failure Hemorrhoids Malignancy

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **26**

Randomization (investigator's opinion)

Randomized

Randomization description

The block randomization method is used Blocking is used to balance the number of samples assigned to each study group, because we have two intervention groups, use equal 4 blocks and create all 4 possible modes and then with Excel software we randomly select a number of blocks. Since the sample size in this study is 26 cases (13 cases in each group), by using Excel software, 7 blocks of 4 are randomly used. The label of interventions to one of the letters A or B and the sequence of randomization determined by the statistical consultant. For allocation concealment,drug delivery and the sequence of randomization is not available to researchers and evaluators while is the responsibility of the off-site individual.

Blinding (investigator's opinion)

Double blinded

Blinding description

After evaluation by the researcher, participants are referred to the off-site individual(drug Delivery Person) and receive A or B intervention according to a random sequence list The drug and placebo are coded in similar capsules and in identical packages, with the same color and participants, researchers, drug Delivery Person and investigators are not aware of treatment allocation. Only the statistician will be unblinded to the treatment assignment.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, 1449614535, Iran

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Postal code

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Approval date

2019-07-27, 1398/05/05

Ethics committee reference number

IR.IUMS.REC.1398.457

Health conditions studied

1

Description of health condition studied

Systolic heart failure

ICD-10 code

I50.22

ICD-10 code description

Chronic 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 Aloe Vera gel
Method of measurement
Minnesota Living With Heart Failure Questionnaire

Secondary outcomes

1

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 Aloe Vera gel
Method of measurement
Six minute walk test

2

Description
Insomnia score in the Insomnia Severity Index (ISI) questionnaire
Timepoint
Measure the insomnia score at the beginning of study (before intervention) and one week after taking intervention (Aloe Vera gel)
Method of measurement
The Insomnia Severity Index (ISI) questionnaire

3

Description
Quality of sleep score in the Pittsburgh Sleep Quality Index (PSQI) questionnaire
Timepoint
Measure the quality of sleep score at the beginning of study (before intervention) and one week after taking intervention (Aloe Vera gel)
Method of measurement
The Pittsburgh Sleep Quality Index (PSQI) questionnaire

4

Description
Obstructive sleep apnea score in STOP-BANG sleep apnea questionnaire
Timepoint
Measure the obstructive sleep apnea score at the beginning of study (before intervention) and one week after taking intervention (Aloe Vera gel)
Method of measurement
STOP-BANG sleep apnea questionnaire

Intervention groups

1

Description
Patients will receive Aloe Vera gel capsule two times a day for next 8 weeks.Each capsule contains 150 mg of Aloe Vera gel . The drug will be provided by Shahid Beheshti university pharmacy lab
Category
Treatment - Drugs

2

Description
Placebo capsule that is identically appearing with Aloe Vera capsule will be administered to patients in placebo group. patients will receive placebo drug two times a day for next 8 weeks. Capsules contain 150 mg starch which will be provided in the Shahid Beheshti university pharmacy lab
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Cardiology clinic, Shahid Sadoughi University of Medical Sciences, Yazd, Iran
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Sponsors / Funding sources

1

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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
Iran 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
Iran University of Medical Sciences

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Position
MD, Ph.D student of Iranian Traditional Medicine

Latest degree
Medical doctor

Other areas of specialty/work
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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