

# 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  $\leq 40\%$  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

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 5558 0388

###### Email address

sabbaghzadegan.s@tak.iums.ac.ir

##### 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  $\leq 40\%$  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  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
۱۴۴۹۶۱۴۵۳۵

**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

#### **Full name of responsible person**

Saeideh Sabbaghzadegan

#### **Street address**

Heart clinic, Jomhoory street, Yazd, Iran

#### **City**

Yazd

#### **Province**

Yazd

#### **Postal code**

8917156735

#### **Phone**

+98 35 1525 6012

#### **Email**

sabbaghzadegan.s@tak.iums.ac.ir

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Iran University of Medical Sciences

#### **Full name of responsible person**

Morteza Naserbakht

#### **Street address**

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

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

۱۳۴۹۶۱۴۵۳۵

**Phone**

+98 21 86701

**Email**

admins@iums.ac.ir

**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

**Full name of responsible person**

Saeideh Sabbaghzadegan

**Position**

MD, Ph.D student of Iranian Traditional Medicine

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

**Street address**

No.847, Beginning of Behesht St, South side of Park City, Vahdat-e Islamic St, Hassan Abad Sq

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۱۱۴۷۳۳۳۱۱

**Phone**

+98 21 5558 0388

**Fax**

**Email**

sabbaghzadegan.s@tak.iums.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr Majid Dadmehr

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

**Street address**

No.847, Beginning of behesht Street, South Park City, Vahdat Islamic Street, Hassan Abad Square

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۱۱۴۷۳۳۳۱۱

**Phone**

+98 21 5563 9667

**Email**

dadmehr.m@iums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Saeideh Sabbaghzadegan

**Position**

MD, Ph.D student of Iranian Traditional Medicine

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

**Street address**

No. 847 , Vahdat-e-Islami St , South side of Park City , Hassan Abad Square, Behesht Street, Faculty of Iranian Medicine

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۱۱۴۷۳۳۳۱۱

**Phone**

+98 21 5563 9667

**Fax**

**Email**

ssbbaghzadegan@gmail.com

## 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