

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Efficacy of Barley water (*Hordeum vulgare*) in clinical outcome of COVID-19 patients hospitalized in Shiraz: a single blind, randomized controlled clinical study

Protocol summary

Study aim

Determining the effect of Barley water in the treatment of clinical symptoms of patients with COVID-19 admitted to Shiraz hospitals

Design

Randomized clinical trial with control group , single blind, phase 2, on 100 patients. Random allocation software 2.0 uses for randomization.

Settings and conduct

The study site is Shiraz hospitals which is selected for patients with Covid-19. The study is single blind. The product is given by the nurse and the researcher is blinded. The duration of use of this product is 14 days. Patients follow up is done for the duration of hospitalization.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with a definitive diagnosis of pneumonia (pneumonitis) caused by COVID 19; Patients are not in the severe group and do not need care in the intensive care unit (ICU care); age > 18; Patients don't receive antiviral medication prior to enrollment; The disease is confirmed by PCR or CT scan. Exclusion criteria :Pregnancy; chronic kidney disease; history of allergy to barley.

Intervention groups

One hundred patients are selected from the target population and randomly divided into two equal groups. Patients in both groups receive current medications for this disease according to the approved protocol, but patients in the intervention group also receive a 250 cc glass of barley water daily (around 11 am).

Main outcome variables

clinical symptoms; duration of recovery of each of the clinical symptoms; rate of improvement of clinical symptoms; duration of hospitalization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150830023823N3**

Registration date: **2020-12-06, 1399/09/16**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-06, 1399/09/16**

Update count: **0**

Registration date

2020-12-06, 1399/09/16

Registrant information

Name

Ali Tavakoli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3233 1028

Email address

tavakkolia@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-15, 1399/08/25

Expected recruitment end date

2020-12-13, 1399/09/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Barley water (*Hordeum vulgare*) in clinical outcome of COVID-19 patients hospitalized in Shiraz: a single blind, randomized controlled clinical study

Public title

Efficacy of Barley water (*Hordeum vulgare*) in clinical outcome of COVID-19 patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with a definitive diagnosis of pneumonia (pneumonitis) caused by COVID 19 according to the national guidelines for the new corona virus that hospitalized in selected hospitals for corona virus in Shiraz. Patients are not in the severe group and do not need care in the intensive care unit (ICU care) age>18 Patients don't receive antiviral medication prior to enrollment. The disease is confirmed by PCR or CT scan.

Exclusion criteria:

Pregnancy Chronic kidney disease History of allergy to barley

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: we use permutation block randomization method with block size of 4. Selected samples based on these blocks are placed in intervention (A) and control (B) groups. 1. AABB 2. ABAB 3. ABBA 4. BBAA 5. BABA 6. BAAB

Blinding (investigator's opinion)

Single blinded

Blinding description

The product is given by the nurse and the Investigator is blinded.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Zand street

City

Shiraz

Province

Fars

Postal code

7183883477

Approval date

2020-05-05, 1399/02/16

Ethics committee reference number

IR.SUMS.REC.1399.216

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Fever

Timepoint

Before and after the intervention In the form of daily

Method of measurement

Thermometer

2

Description

Cough

Timepoint

daily

Method of measurement

Patient history

3

Description

Respiratory rate

Timepoint

daily

Method of measurement

visual by nurse

4

Description

Chills

Timepoint

daily

Method of measurement

Patient history

5**Description**

Body pain

Timepoint

daily

Method of measurement

Patient history with Visual Analog Scale

6**Description**

duration of hospitalization

Timepoint

daily

Method of measurement

patient chart

Secondary outcomes**1****Description**

duration of recovery of each of the clinical symptoms(fever, dry cough, respiratory rate)

Timepoint

daily

Method of measurement

clinical symptoms registration form according to the national guidelines of the new corona virus

2**Description**

side effect such as nausea, bloating and constipation

Timepoint

daily

Method of measurement

drug side effect registration form

3**Description**

CRP

Timepoint

Start and end of the intervention

Method of measurement

Biochemical Auto analyzer Instrument

Intervention groups**1****Description**

Intervention group: current medications for this disease according to the approved protocol, in addition to 250 cc of barley water daily (around 11 am).

Category

Treatment - Other

2**Description**

Control group: current medications for this disease according to the approved protocol

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ali Asghar Hospital

Full name of responsible person

Ali Tavakoli

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Meshkin Fam Street

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Abbas Rezaianzadeh

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Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Ali Tavakoli

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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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

Not applicable