Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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
Street address
Meshkin Fam Street
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71439-18796
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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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Postal code
71348-14336
Phone
+98 71 3235 7282
Email
vcrdep@sums.ac.ir
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
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Person responsible for updating data

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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