Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Efficacy of the barley-based remedy in the treatment of suspected novel coronavirus (COVID-19) pneumonia

Protocol summary

Study aim
Determination the efficacy of barley-based remedy in the treatment of suspected novel coronavirus pneumonia (COVID-19)
Design
A randomized controlled clinical trial with parallel groups
Settings and conduct
Patients with mild to moderate disease who visit the clinics designated by the Department of Health for Covid-19, are a quarantine candidate and receive home treatment.
Participants/Inclusion and exclusion criteria
patients with 18-65 years old, developing mild to moderate COVID-19 based on Ministry of Health protocol and candidate for outpatient treatment include to this study and those with asthma or allergy, hypertension, diabetes, pregnancy/lactation, CHF, chronic renal failure, chemotherapy, taking Corticosteroid, immune deficiency do not include.
Intervention groups
Intervention group: Receiving medication for treatment of Covid-19 based on Ministry of Health protocol with barley based-compound Control group: receive medication for treatment of Covid-19 according to Ministry of Health protocol
Main outcome variables
clinical status

General information

Reason for update
Editing sample size
Acronym
IRCT registration information
IRCT registration number: **IRCT20180923041093N4**
Registration date: **2020-03-28, 1399/01/09**
Registration timing: **prospective**
Last update: **2020-06-06, 1399/03/17**
Update count: **1**
Registration date
2020-03-28, 1399/01/09

Registrant information
Name
Fatemeh sadat Hasheminasab
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-04-02, 1399/01/14
Expected recruitment end date
2020-05-03, 1399/02/14
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficacy of the barley-based remedy in the treatment of suspected novel coronavirus (COVID-19) pneumonia

Public title
Efficacy of the barley-based remedy in the treatment of novel corona
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

18-65 years old Developed mild to moderate COVID-19 based on Ministry of Health protocol Candidate for outpatient treatment

Exclusion criteria:

Asthma or allergy Hypertension Diabetes Pregnancy/lactation CHF Chronic renal failure ChemotherapyT aking Corticosteroid Immune deficiency

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be selected according to the inclusion criteria and then randomly assigned to the experimental and control groups according to the random sequence obtained through random allocation software.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Beginning of Ibn Sina Street, Beginning of Jihad Blvd., Somayeh Road (Tahmasebabad), Kerman

City

Kerman

Province

Kerman

Postal code

584-76175

Approval date

2020-02-22, 1398/12/03

Ethics committee reference number

IR.KMU.REC.1399.014

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19

Primary outcomes

1

Description

Temperature

Timepoint

0-1-2-3-4-7-14 days after starting intervention

Method of measurement

Termometer

2

Description

Cough (severity-frequency)

Timepoint

0-1-2-3-4-7-14 days after starting intervention

Method of measurement

Fisman Cough Severity Score

3

Description

Weakness

Timepoint

0-1-2-3-4-7-14 days after starting intervention

Method of measurement

Asking patients using visual analog scale (VAS)

4

Description

Muscular pain

Timepoint

0-1-2-3-4-7-14 days after starting intervention

Method of measurement

Asking patients using visual analog scale (VAS)

5

Description

Respiratory rate

Timepoint

0-1-2-3-4-7-14 days after starting intervention

Method of measurement

Counting the number of breaths per minute

Secondary outcomes

1

Description

Hospital admission

Timepoint

0-1-2-3-4-7-14 days after starting intervention

Method of measurement

Ratio of the number of admission to total patients in each group

2

Description

Mortality

Timepoint

0-1-2-3-4-7-14 days after starting intervention

Method of measurement

Ratio of the number of deaths to total patients in each group

Intervention groups

1

Description

Intervention group: Patients in this group receive the treatment according to the protocol of the Ministry of Health, in addition they should daily boil the contents of one drug pack with 8 glasses of water slowly to stay two glasses, then smooth and the content of the sachet will be added for 5 days. They drink a glass in the morning and a glass in the evening.

Category

Treatment - Drugs

2

Description

Control group: Patients in this group receive medication according to the Ministry of Health protocol.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Hospital

Full name of responsible person

Maryam Azimi

Street address

AfzaliPour Hospital, Adjacent to Bahonar University, AfzaliPour Landscape, Imam highway, Kerman

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhti

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Kerman university of medical sciences, Haft-Bagh Highway

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abpardakhty@kmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Maryam Azimi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
After the completion of the study, the information on the main outcome will be shared
When the data will become available and for how long
10 months after printing
To whom data/document is available
All researchers can take action
Under which criteria data/document could be used
Data and results will be available to all researchers for research on diabetes
From where data/document is obtainable
dr.azimm@gmail.com
What processes are involved for a request to access data/document
The data will be provided to the applicant after a review and approval of the request within a month
Comments