Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of licorice as an adjunct treatment for patients with Covid-19 admitted to the intensive care unit: A randomized, placebo-controlled, double-blind clinical trial

Protocol summary

Study aim
Evaluation of the effect of licorice compare to placebo as adjunctive therapy in patients with Covid-19 admitted to intensive care units

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 60 patients. For randomization, we will use the restricted randomization method of block randomization.

Settings and conduct
Setting: Intensive care units of Al-Zahra Hospital in Isfahan. Intervention: Eligible patients will be randomly divided into two groups of standard treatment with placebo or de-regis (licoric) tablets. The mean duration of discharge from the intensive care unit, as well as the rate of recovery of clinical symptoms of Covid-19, the duration of hospitalization in the intensive care unit, the duration of mechanical ventilation, and the amount of SOFA on days 1,3,5 will be assessed.

Participants/Inclusion and exclusion criteria
Patients with Covid-19 admitted to the intensive care unit will be included. Patients with high blood pressure, congestive heart failure, severe liver, kidney and thyroid disease, concomitant use of some drugs such as warfarin will not be included in the study.

Intervention groups
Eligible patients receive the usual Covid treatments along with D-reglis tablets or placebo at the dose of 760 mg per day for 5 days.

Main outcome variables
The main outcome is the average duration of discharge from the intensive care unit compared to the intervention and control groups.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20081208001497N10**
Registration date: **2022-02-26, 1400/12/07**
Registration timing: **prospective**

Last update: **2022-02-26, 1400/12/07**
Update count: **0**

Registration date
2022-02-26, 1400/12/07

Registrant information

Name
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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
2022-03-05, 1400/12/14

Expected recruitment end date
2022-09-21, 1401/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of licorice as an adjunct treatment for patients with Covid-19 admitted to the intensive care unit: A randomized, placebo-controlled, double-blind clinical trial

Public title
Evaluation of the effect of licorice as an adjunctive therapy for patients with Covid-19 admitted to the intensive care unit

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Covid-19 diagnosis based on PCR test Hospitalized in the intensive care unit and under mechanical ventilation

Exclusion criteria:
1. Patients with high blood pressure (<90/140) Patients with congestive heart failure Patients with severe liver, kidney and thyroid disease Concomitant use of warfarin, SSRI, MAOI, diuretics, antiarrhythmic drugs Treatment with antiviral drugs one month before entering the study Allergy to licorice Pregnancy and lactation Dissatisfaction of the patient or his legal guardian Infected with Covid-19 for at least 20 days prior to enrollment

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples will be randomized by random blocking method with blocks of 4 which generated by Random Allocation software version 2. Blocking and allocation sequence for concealment will be done by the person not involved in the research (Allocation Concealment). The sample allocation ratio will be (1: 1 Allocation) and will be divided into two groups of drug recipients and placebo (Assignment). Drugs will then be given to patients based on the blocks obtained and in the order of allocation.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study will be performed as double-blind. The drug and placebo packing package and code allocation is done by the researcher involved in the research and then provided to the main researcher. In this way, the physician and patients will not know the contents of the packages and the type of codes and will not know which of the two control or test groups it belongs to.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences, P.O. Box 319, Hezar-Jerib Ave.

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Province
Isfehan

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81746 73461

Approval date
2022-02-20, 1400/12/01

Ethics committee reference number
IR.MUI.RESEARCH.REC.1400.478

Health conditions studied

1

Description of health condition studied
Covid-19

ICD-10 code
U07.1

ICD-10 code description
U07.1 COVID-19, virus identified

Primary outcomes

1

Description
Average time out of intensive care unit

Timepoint
After discharge

Method of measurement
Number of hospitalization days

Secondary outcomes

1

Description
Speed of recovery of Covid-19 clinical signs

Timepoint
The first and fourteenth day

Method of measurement

Percentage of improvement in symptoms

2

Description
Duration of hospitalization in the intensive care unit
Timepoint
After discharge or death
Method of measurement
Number of days of hospitalization

3

Description
Duration of mechanical ventilation
Timepoint
During hospitalization
Method of measurement
Number of days under mechanical ventilation

Intervention groups

1

Description
Intervention group: Eligible patients receive 760 mg / day (equivalent to two tablets) d-reGliss (Iran Darok) for five days. Patients will receive other routine Covid-19 treatments according to the hospital protocol.
Category
Treatment - Drugs

2

Description
Control group: They receive the usual treatments along with placebo pills. This pill is prepared by Iran Darok Pharmaceutical Company and contains exponents such as lactose and magnesium stearate without active ingredient.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Sarah Mousavi
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
3400852
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
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Sarah Mousavi
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
Yes - There is 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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Published article

When the data will become available and for how long
One year

To whom data/document is available
All people

Under which criteria data/document could be used
No condition

From where data/document is obtainable
Scientific responded of the study

What processes are involved for a request to access data/document
Scientific responded of the study

Comments