

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 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

Sarah Mousavi

Name of organization / entity

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Isfahan University of Medical Sciences

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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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Isfahan

Province

Isfahan

Postal code

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

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Research deputy of Isfahan University of Medical Sciences

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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

Full name of responsible person

Sarah Mousavi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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