

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The effect of Rosa Damascena extract in treatment of COVID-19 patients in kosar hospital, Semnan

Protocol summary

Study aim

The effect of Rosa Damascena extract in treatment of COVID-19 patients in kosar hospital, Semnan

Design

Clinical trial with parallel control group, double blind, randomized, Control with placebo, single center trial, Sample size 20 people.

Settings and conduct

In this study we will enroll 10 patients with COVID-19 who will be consequently admitted to semnan hospital. The patients will receive 5 cc of rose water in spite of drugs suggested by Iranian Health ministry management guidelines and patients in the control group will receive water. all the patients will be followed for one week and the mortality rate, the number of recovered or discharged patients and the need for ICU admission in control and intervention group will compare.

Participants/Inclusion and exclusion criteria

Patients with COVID-19 who are older than 18 years old

Intervention groups

Intervention group: To 10 patients with COVID-19 who are admitted to kosar hospital. In addition to the usual protocols of the Ministry of Health, patients will be given 5 cc of rose water (Factory Construction Barij Essence) in a glass of water every 8 hours for a week. Control group: Patients are treated according to national protocol and received water.

Main outcome variables

The mortality rate, the recovered or discharged rate, ICU admission

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200402046917N1**

Registration date: **2020-08-31, 1399/06/10**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-31, 1399/06/10**

Update count: **0**

Registration date

2020-08-31, 1399/06/10

Registrant information

Name

maliheh Ghadir

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3665 3309

Email address

ghadirm12@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2020-10-22, 1399/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Rosa Damascena extract in treatment of COVID-19 patients in kosar hospital, Semnan

Public title

therapeutic effect of Rosa Damascena extract in treatment of COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients diagnosed with COVID-19 according to history, physical exam, radiological findings and PCR test of nasopharynx and oropharynx

Exclusion criteria:

patients who need invasive positive pressure ventilation or ICU care during 24h from their admission

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

A double-blind study is performed and patients and health care providers and patient recovery assessors as well as primary data analyzers do not know who is in the control group and who is in the main group and the recipient of the extract.

Placebo

Used

Assignment

Parallel

Other design features

during the study the clinical status, the improvement of patients' condition, the need for ICU care, and mortality will be evaluated according to a questionnaire.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2020-07-05, 1399/04/15

Ethics committee reference number

IR.SEMUMS.REC.1399.106

Health conditions studied

1

Description of health condition studied

Covid-19

ICD-10 code

U07.01

ICD-10 code description

Covid-19 infection

Primary outcomes

1

Description

Mortality rate

Timepoint

After 7 days

Method of measurement

Questionnaire, Patient data and physician

2

Description

Recovery or discharge rate

Timepoint

After 7 days

Method of measurement

Questionnaire, Patient data and physician

3

Description

ICU admission

Timepoint

After 7 days

Method of measurement

Questionnaire, Patient data and physician

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: To 10 patients with COVID-19 who are admitted to kosar hospital. In addition to the usual protocols of the Ministry of Health, patients will be given 5 cc of rose water (Factory Construction Barij Essence) in a glass of water every 8 hours for a week.

Category

Treatment - Other

2

Description

Control group: Patients are treated according to national protocol and receive water.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar Hospital

Full name of responsible person

Maliheh Ghadir

Street address

semnan, Basij highway

City

semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3344 0021

Email

ghadirm12@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Malihe ghadir

Street address

semnan basij highway

City

semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3344 0021

Email

alizadehbio@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan 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

Karaj University of Medical Sciences

Full name of responsible person

Maliheh Ghadir

Position

Consultant

Latest degree

Subspecialist

Other areas of specialty/work

endocrinology

Street address

No 65, 12ed West Vahdat Avenue, Vahdat Town, Karaj, Alborz Province, Iran

City

Karaj

Province

Alborz

Postal code

3165867774

Phone

+98 26 3665 3309

Email

ghadirm12@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Maliheh Ghadir

Position

consultant

Latest degree

Subspecialist

Other areas of specialty/work

endocrinology

Street address

No. 65, 12ed west Ave., Vahdat Town, Karaj, Alborz province, Iran

City

Karaj

Province

Alborz

Postal code

3165867774

Phone

+98 26 3665 3309

Email

ghadirm12@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Akram alizadeh

Position

Asistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Tissue engineering

Street address

Semnan basij highway

City

semnan

Province

Semnan

Postal code

3165867774

Phone

+98 23 3344 0021

Fax**Email**

alizadehbio@gmail.com

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

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

filled patients' questionnaires

When the data will become available and for how long

after publication

To whom data/document is available

all of the researchers

Under which criteria data/document could be used

they will be available just for clearance and approval of the results

From where data/document is obtainable

Maliheh Ghadir

What processes are involved for a request to access data/document

It will take one week after receiving the email

Comments