Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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 naso pharynx and oro pharynx

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
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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
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semnan basij highway
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Postal code
3514799442
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+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
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Person responsible for scientific inquiries

Contact
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Karaj University of Medical Sciences
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Position
consultant
Latest degree
Subspecialist
Other areas of specialty/work
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Postal code
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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
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City
semnan

Province
Semnan

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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