

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Evaluation of the efficacy of Silymarin nanomicelles in hospitalized patients with COVID-19

Protocol summary

Study aim

Evaluation of the effect of silymarin nanomicels as adjuvant therapy on Covid patients 19

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 50 patients. random.org was used for randomization.

Settings and conduct

This research will be conducted in Imam Reza Hospital of Mashhad and Imam Reza Hospital of AJA. The clinical trial research will be performed on 50 patients in a double-blind manner, and the placebo will be exactly the same as the main drug in terms of shape and color. Patients, physicians, and nurses who evaluate the outcomes will be blind to the groups studied.

Participants/Inclusion and exclusion criteria

inclusion criteria: - patients with the clinical diagnosis or laboratory of covid-19, and have an indication for hospitalization. age between 18 to 75 -Signing an informed consent form exclusion criteria: - Pregnancy and lactation - Active liver disease - Severe renal failure GFR <30 ml/min - Inability of the patient to swallow oral medication

Intervention groups

Intervention group: COVID-19 pneumonia receiving standard of care as per Ministry of Health Protocol of Treatment + Silymarin nanomicelles 70 mg from Nano Exir Sina Company/ three times a day control group: COVID-19 pneumonia receiving standard of care as per Ministry of Health Protocol of Treatment + placebo which is the same in shape and taste from Nano Exir Sina Company/ three times a day

Main outcome variables

1.time to clinical improvement 2.length of Hospitalization 3.mortality rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201024049130N1**

Registration date: **2021-06-21, 1400/03/31**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-21, 1400/03/31**

Update count: **0**

Registration date

2021-06-21, 1400/03/31

Registrant information

Name

Hossein Aryan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3725 3085

Email address

h.aryanmd@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-31, 1400/03/10

Expected recruitment end date

2021-11-22, 1400/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of Silymarin nanomicelles in hospitalized patients with COVID-19

Public title

Evaluation of the efficacy of Silymarin in patients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with clinical or laboratory diagnosis of covid-19 should be hospitalized based on the opinion of a specialist physician. age between 18 to 75 Signing an informed consent form

Exclusion criteria:

Pregnancy and lactation Active liver disease Severe renal failure GFR <30 ml/min Inability of the patient to swallow oral medication

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization using random.org will implemented. For 50 patients, it is randomly selected by site number 1 or 2. Based on this, these patients enter the intervention or control group and receive medication or placebo. In this way, placebo and silymarin drugs are placed inside numbered boxes and none of the doctors, nurses and researchers have any information about the contents of the boxes.

Blinding (investigator's opinion)

Double blinded

Blinding description

The research is double-blind and the drugs are the same in terms of size, shape and smell in the intervention and control groups. Study participants, physicians and nurses who evaluate the outcomes will be blind to the intervention and studied groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of artesh University of Medical Sciences

Street address

West Fatemi St, Etemad Zadeh St. Aja University of Military Medical Sciences. Tehran, Iran

City

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Postal code

1411718541

Approval date

2021-03-02, 1399/12/12

Ethics committee reference number

IR.AJAUMS.REC.1399.250

Health conditions studied

1

Description of health condition studied

Patients with COVID-2019

ICD-10 code

U07.01

ICD-10 code description

COVID-19

Primary outcomes

1

Description

time to clinical improvement

Timepoint

28 days from study enrollment

Method of measurement

Instrument name: Ordinal Scale for Clinical Improvement. The Sequential Clinical Recovery Scale is used by the World Health Organization for Covid patients. This scale contains 8 scores. the scores include: 1. Not hospitalized, no limitations on activities 2. Not hospitalized, limitation on activities 3. Hospitalized, not requiring supplemental oxygen 4. Hospitalized, requiring supplemental oxygen by mask or nasal prongs 5. Hospitalized, on non-invasive ventilation or high flow oxygen devices 6. Hospitalized, on invasive mechanical ventilation 7. Hospitalized, on invasive mechanical ventilation + additional organ support (pressors, RRT, ECMO) 8. Death

Secondary outcomes

1

Description

Mortality

Timepoint

28 days from study enrollment

Method of measurement

All cause mortality (ACM)

2

Description

length of Hospitalization

Timepoint

Hospitalization time at the discretion of the physician

Method of measurement

days

Intervention groups

1

Description

Intervention group: patients with COVID-19 in addition to a standard regimen (Includes dexamethasone and remdesivir and in case of suspected bacterial superinfection with parental antibiotics) will receive Silymarin nanomicelles orally 70 mg from Nano Exir Sina Company/ three times a day

Category

Treatment - Drugs

2

Description

Control group: 25 patients will receive only standard regimen of COVID-2019 (Includes dexamethasone and remdesivir and in case of suspected bacterial superinfection with parental antibiotics) + The placebo is made by Nano Sina Elixir Company, which is exactly the same in terms of appearance, taste and dose.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Hossein Aryan

Street address

Razavi Khorasan Province, Mashhad, Fallahi Boulevard

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2

Recruitment center

Name of recruitment center

Imam Reza Hospital of AJA

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Artesh 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

Artesh University of Medical Sciences

Full name of responsible person

Hossein Aryan

Position

general practitioner

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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Phone

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available