Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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+98 51 3725 3085

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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
Tehran
Province
Tehran
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
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Razavi Khorasan Province, Mashhad, Fallahi Boulevard
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Recruitment center
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Sponsors / Funding sources

1

Sponsor
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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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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