

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Acetylcysteine for the Prevention of Liver Injury in Covid-19 Intensive Care Unit Patients Under Treatment with Remdesivir: A Double-Blind, Placebo-Controlled Randomized Clinical Trial

Protocol summary

Study aim

1. To compare serum levels of liver aminotransferases, bilirubin and prothrombin time between Covid-19 patients receiving remdesivir with and without simultaneous acetylcysteine therapy 2. To compare the incidence of acute liver injury between Covid-19 patients receiving remdesivir with and without simultaneous acetylcysteine therapy

Design

A double-blind, placebo-controlled randomized clinical trial. Patients will be randomized using QuickCalcs random-number calculators (2018 GraphPad Software, LLC; San Diego, CA).

Settings and conduct

Intensive care unit of Imam Reza Hospital (501 Hospital, AJA University of medical Sciences)

Participants/Inclusion and exclusion criteria

All patients aged above 18 years admitted in intensive care unit with definite diagnosis of Covid-19 under treatment with remdesivir will be included. Criteria of exclusion will be: 1. Positive history of any underlying liver disease 2. Plasma levels of liver transaminases over 100 IU/L on the first day of ICU admission 3. Simultaneous use of any hepatotoxic drugs

Intervention groups

One gram acetylcysteine will be administered intravenously every 12 hours for each patient in the intervention group, and each patient in the placebo group will receive the same volume of 0.9% sodium chloride.

Main outcome variables

Outcome of interest will be considered as any significant difference in serum levels of aspartate aminotransferase, alanine aminotransferase, bilirubin, prothrombin time or incidence rate of acute liver injury between intervention and placebo groups on the second, third, fourth or fifth day of trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210726051995N1**

Registration date: **2021-08-15, 1400/05/24**

Registration timing: **registered_while_recruiting**

Last update: **2021-08-15, 1400/05/24**

Update count: **0**

Registration date

2021-08-15, 1400/05/24

Registrant information

Name

Ebrahim Hazrati

Name of organization / entity

AJA University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-27, 1400/05/05

Expected recruitment end date

2021-09-27, 1400/07/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Acetylcysteine for the Prevention of Liver Injury in Covid-19 Intensive Care Unit Patients Under Treatment with Remdesivir: A Double-Blind, Placebo-Controlled Randomized Clinical Trial

Public title

Acetylcysteine for the Prevention of Liver Injury in Covid-19 Patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosed positive for Covid-19 based on PCR testing
Admitted in intensive care unit Treated with remdesivir

Exclusion criteria:

Positive history of any underlying liver disease e.g. fatty liver, or acute or chronic hepatitis Plasma levels of liver transaminases over 100 IU/L on the first day of ICU admission Simultaneous use of any hepatotoxic drugs

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

QuickCalcs random-number calculators (2018 GraphPad Software, LLC; San Diego, CA) will be used for randomization. In this regard, patients will receive random numbers of 0 or 1 generated by the software, and will be included into either intervention or control groups accordingly.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study patients, principle investigator, responsible physician and the intensive care unit nursing staff will stay blinded until the end of the trial. Only the chief pharmacist will be aware of the patients' groups, and will provide medications to the nursing staff in identical individually numbered packs, containing either acetylcysteine or normal saline (placebo) according to the sequential order of the randomization.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics committee of AJA University of Medical Sciences

Street address

AJA University of Medical Sciences, Etemadzadeh Ave., West Fatemi St., Tehran, Iran

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Postal code

1411718541

Approval date

2021-07-26, 1400/05/04

Ethics committee reference number

IR.AJAUMS.REC.1400.092

Health conditions studied

1

Description of health condition studied

COVID-19 pneumonia

ICD-10 code

J12.81

ICD-10 code description

Pneumonia due to SARS-associated coronavirus

2

Description of health condition studied

Acute liver injury

ICD-10 code

K72.0

ICD-10 code description

Acute and subacute hepatic failure

Primary outcomes

1

Description

the prevention of acute liver injury

Timepoint

Days 1, 2, 3, 4 and 5 of trial

Method of measurement

Laboratory measurement of serum levels of liver aminotransferases

Secondary outcomes

1

Description

Total bilirubin serum levels

Timepoint

Days 1, 2, 3, 4 and 5 of trial

Method of measurement

Laboratory measurement

2

Description

Prothrombin time

Timepoint

Days 1, 2, 3, 4 and 5 of trial

Method of measurement

Laboratory measurement

Intervention groups

1

Description

Intervention group: including 44 patients who will receive 1000 mg of acetylcysteine intravenously every 12 hours for 5 days.

Category

Treatment - Drugs

2

Description

Control group: including 44 patients who will receive placebo (Normal Saline, 0.9%) intravenously every 12 hours for 5 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Pouria Mousapour

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Imam Reza Hospital, Etemadzadeh Ave., West Fatemi St., Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Mojtaba Yousefi Zoshk

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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

Ebrahim Hazrati

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Intensive care

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Person responsible for scientific inquiries

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Pouria Mousapour

Position

General practitioner

Latest degree

Medical doctor

Other areas of specialty/work

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Latest degree

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Other areas of specialty/work

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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

No - There is not 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

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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