Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

Acetylcysteine for the Prevention of Liver Injury in Covid-19 Intensive Care Unit Patients Under Treatment with Remdisivir: 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, forth 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 Remdisivir: 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 hepaptitis 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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Tehran

Province
Tehran

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
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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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Position
General practitioner

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Medical doctor

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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
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