Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Evaluation of the effect of Silymarin on hepatotoxicity induced by Remdesivir in patients with COVID-19 admitted to Shahrekord hospitals

Protocol summary

Study aim
Determination of the effect of silymarin on rhodsivider-induced hepatotoxicity in patients with COVID-19 admitted to Shahrekord hospitals

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, on 70 patients. Excel software rand function was used for randomization.

Settings and conduct
This research project is a quasi-experimental study in which 70 people with inclusion criteria in this study are randomly divided into two intervention groups of 35 people and control of 35 people. The recent study is double blind randomized clinical trial and will be performed in Hajar Hospital in Shahrekord, Iran. Liver samples are measured before entering the study on a daily basis and also on the seventh day of the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients with positive PCR test who have been treated with RamedSavier; SpO2 blood oxygen saturation level less than 93% in room air or patients in need of supportive oxygen or mechanical ventilation; patients with pulmonary infiltration in radiological studies; absence of underlying liver disease such as liver cirrhosis and viral hepatitis, etc. according to the history taken. 5. Liver enzymes less than 5 times normal

Intervention groups
The first group of Remdesivir + Livergol 140 mg 3 times a day for 1 week; the second group received Remdesivir + placebo 3 times a day for 1 week.

Main outcome variables
Main outcome variables include ALT; AST; ALP; BILL total; BILL direct.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201227049854N1**
Registration date: **2021-07-11, 1400/04/20**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-11, 1400/04/20**
Update count: **0**

Registration date
2021-07-11, 1400/04/20

Registrant information

Name
Saeed Badiei
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 3264 4568
Email address
saeedbadiei@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-02-19, 1399/12/01

Expected recruitment end date
2021-07-23, 1400/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of Silymarin on hepatotoxicity induced by Remdesivir in patients with COVID-19 admitted to Shahrekord hospitals

Public title
Evaluation of the effect of silymarin on hepatotoxicity induced by Remdesivir
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with positive covid19 PCR test who have been treated with Remdesivir Spo2<93% Patient with lung infiltration Absence of underlying liver disease Liver enzymes less than 5 times normal
Exclusion criteria:
Increased liver enzymes more than 5 times normal Patient dissatisfaction Pregnant or lactating patients Patients with glomerular filtration less than 50 mg / min
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly divided into one of three groups: A (patient 1 to 35), group B (36 to 70), and group C (71 to 105).
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, residents, patients, and statistical counselors are kept blind.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Shahrekord University of Medical Sciences
Street address
Shahrekord University of Medical Sciences, Kashani St.
City
shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Approval date
2020-12-23, 1399/10/03
Ethics committee reference number
IR.SKUMS.REC.1399.198

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.1
ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Direct Billirubin
Timepoint
Measurement of liver enzymes on the first and seventh days of the study
Method of measurement
Measurement of liver enzymes by BT 3500 device

2

Description
Total Billirubin
Timepoint
Measurement of liver enzymes on the first and seventh days of the study
Method of measurement
Measurement of liver enzymes by BT 3500 device

3

Description
Aspartate Aminotransferase
Timepoint
Measurement of liver enzymes on the first and seventh days of the study
Method of measurement
Measurement of liver enzymes by BT 3500 device

4

Description
Alanine Aminotransferase
Timepoint
Measurement of liver enzymes on the first and seventh days of the study
Method of measurement
Measurement of liver enzymes by BT 3500 device

5

Description
Alkaline Phosphatase
Timepoint
Measurement of liver enzymes on the first and seventh days of the study
Method of measurement
Measurement of liver enzymes by BT 3500 device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Remdesivir + Livergel 140 mg 3 times a day for 1 week.
Category
Treatment - Drugs

2

Description
Control group: Remdesivir + placebo 3 times a day for 1 week
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hajar Hospital in Shahrekord
Full name of responsible person
Zahra Habibi
Street address
Hajar Hospital, Parastar Street
City
Shahrekord
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8816754633
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Fax
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Email
Hajar-Hospital@skums.ac.ir
Web page address
https://hajarhp.skums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Mehraban Sadeghi
Street address
Kashani St. Headquarters of Shahrekord University of Medical Sciences
City
Shahrekord
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Chahar-Mahal-va-Bakhtiari
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8815713471
Phone
+98 38 3334 2414
Email
vcrt@skums.ac.ir
Web page address
https://research.skums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Zahra Habibi
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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Person responsible for scientific inquiries

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Full name of responsible person

Zahra Habibi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Saeed Badiei

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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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

Yes - There is 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

Information about the main outcome can be shared.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Dr. Zahra Habibi

Under which criteria data/document could be used

The documents can be used after printing the results

From where data/document is obtainable

The data can be used by referring to the e-mail address

What processes are involved for a request to access data/document

Access period starts 6 months after the results are published

Comments