

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 rhodovir-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 RamedSavir; 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 + Livregol 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

saeedbadei@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

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816754633

Phone

+98 38 3222 0016

Fax

+98 38 3224 3715

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

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Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

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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

Street address

Hajar Hospital, Parastar Street

City

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Zahra Habibi

Position

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Person responsible for updating data

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Saeed Badiei

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

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Postal code

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Phone

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Email

saeedbadei@yahoo.com

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