

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of therapeutic effect of Simospan syrup (contains of Thymus vulgaris, Hedera helix, Honey and Vitamin C) on duration of hospitalization in covid-19 patients

Protocol summary

Study aim

Evaluation of the therapeutic effect of Simospan syrup (contains Thymus vulgaris, Hedera helix, Honey, and Vitamin C) on the duration of hospitalization of covid-19 patients

Design

The current study is a clinical trial with a control group, randomized, single-blind on 52 patients (26 patients in each group).

Settings and conduct

Sampling will be done in Vasei hospital. After obtaining conscious consent from qualified patients, first, all of them in terms of the main clinical variable (pulmonary function test) matched and then randomly divided into control and intervention groups. Treatment time is considered 5 days.

Participants/Inclusion and exclusion criteria

Inclusion criteria: hospitalized patients diagnosed with covid-19; age between 30-60 years; the amount of oxygen saturation below 93%. Exclusion criteria: pregnancy; lactation; organ damage.

Intervention groups

control group: receive routine treatment based on physician's order. intervention group: receive routine treatment based on physician's order and receive simospan syrup

Main outcome variables

laboratory parameters, duration of hospitalizations, and the spent time to the improvement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210621051642N1**
Registration date: **2021-07-05, 1400/04/14**

Registration timing: **registered_while_recruiting**

Last update: **2021-07-05, 1400/04/14**

Update count: **0**

Registration date

2021-07-05, 1400/04/14

Registrant information

Name

Sajad Seyedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4401 1954

Email address

sajadseyedi2004@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-26, 1400/04/05

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of therapeutic effect of Simospan syrup (contains of Thymus vulgaris, Hedera helix, Honey and Vitamin C) on duration of hospitalization in covid-19 patients

Public title

Evaluation of therapeutic effect of Simospan syrup on covid-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age limitation (30-60 years old) Hospitalized patients with CT-scan findings in favor of Covid-19 disease Hospitalized patients with the amount of blood oxygen saturation below 93% Hospitalized patients with Chest X-ray findings in favor of pneumonia Hospitalized patients without underlying disease

Exclusion criteria:

Pregnancy and lactation End-stage Covid-19 patients Patients diagnosed with underlying disease and organ damage

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done based on the table of random numbers using Excel software and with the Randbetween command between 52 samples. The control group(A) does not receive any treatment over common treatment. The 26 numbers of intervention group(B) receives the simospan syrup,. Patients numbers from 000-026 and 027-052 are considered for groups A and B respectively.

Blinding (investigator's opinion)

Single blinded

Blinding description

Analyser and data collecting man not be aware of intervention type and participants in control and intervention groups. so the trial will be run as single-blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

Street address

Nuclear martyrs boulevard-Above the memorial of the anonymous martyrs-sabzevar university of med-sci pardis

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913114

Approval date

2021-06-20, 1400/03/30

Ethics committee reference number

IR.MEDSAB.REC.1400.044

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

The spent time to illness improvement

Timepoint

Before and 5 days after the start of intervention

Method of measurement

Variable type is qualitative and its scale is nominal. the criterion of recovery records and descripts based on observations of data collecting man in checklist. relative criterion based on clinical symptoms: 1-non-admission along with the return of normal activity-2-non-admission along without the return of normal activity-3-admission without the need for oxygentherapy-4-admission with the need for oxygentherapy-5-admission with the need to receive high speed oxygen from the nose or non invasive ventilation or both-6-admission with the need to receive oxygen therapy with invasive ventilation or oxygen therapy from non pulmonary pathways or both-7-patient's death

2

Description

Discharge from hospital

Timepoint

After the start of intervention

Method of measurement

Duration of hospitalization

Secondary outcomes

1

Description

The blood level of ALT enzyme

Timepoint

Before and 5 days after the start of intervention

Method of measurement

Spectrometer

2

Description

The blood level of BUN

Timepoint

Before and 5 days after the start of intervention

Method of measurement

Spectrometer

3

Description

The blood level of creatinine

Timepoint

Before and 5 days after the start of intervention

Method of measurement

Spectrometer

4

Description

The blood level of AST enzyme

Timepoint

Before and 5 days after the start of intervention

Method of measurement

Spectrometer

5

Description

RBC count

Timepoint

Before and 5 days after the start of intervention

Method of measurement

Cell counter

6

Description

WBC count

Timepoint

Before and 5 days after the start of intervention

Method of measurement

Cell counter

7

Description

The blood level of HG

Timepoint

Before and 5 days after the start of intervention

Method of measurement

Auto analyzer machine

8

Description

The blood level of HCT

Timepoint

Before and 5 days after the start of intervention

Method of measurement

Auto analyzer machine

9

Description

CRP blood test

Timepoint

Before and 5 days after the start of intervention

Method of measurement

ELISA kits

10

Description

ESR test

Timepoint

Before and 5 days after the start of intervention

Method of measurement

Wintrobe method

Intervention groups

1

Description

Control group: routine treatment based on physician's order

Category

Treatment - Other

2

Description

Intervention group: routine treatment based on physician's order and simospan syrup (every 8 hours 6 cc for 5 days)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Vasei hospital

Full name of responsible person

Sajad Seyedi

Street address

Nuclear martyrs boulevard-

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Vasei Hospital clinical research development center
Street address
Vasei Hospital,Nuclear martyrs Blvd
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Postal code
9617747431
Phone
+98 51 4465 1300
Email
CRDC@medsab.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sabzevar 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
Sabzevar University of Medical Sciences
Full name of responsible person
Sajad Seyedi
Position
Hospital pharmacist
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address

Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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Position
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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

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