

# 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-

**City**

Sabzevar

**Province**

Razavi Khorasan  
**Postal code**  
9617747431  
**Phone**  
+98 51 4466 5721  
**Email**  
sajadseyedi2004@gmail.com

Heshmatieh hospital, Asadabadi street  
**City**  
Sabzevar  
**Province**  
Razavi Khorasan  
**Postal code**  
9613873140  
**Phone**  
+98 51 4401 1954  
**Email**  
sajadseyedi2004@gmail.com

## 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  
**City**  
Sabzevar  
**Province**  
Razavi Khorasan  
**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

#### 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**  
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**Street address**  
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**Phone**  
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**Email**  
sajadseyedi2004@gmail.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Sabzevar University of Medical Sciences  
**Full name of responsible person**  
Sajad Seyedi  
**Position**  
Hospital pharmacist  
**Latest degree**  
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**Email**

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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