

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Evaluation and comparison of the effectiveness of three herbal products containing Noscapine (Opiucough, Noscough and Noscatem) on clinical symptoms and para-clinical parameters in adults hospitalized with severe COVID-19

#### Protocol summary

##### Study aim

Evaluation of the effectiveness of three herbal products containing noscapine (opiucough and noscatem and noscough) in the treatment of patients with COVID 19 as well as reduction of mortality or disability due to (SARS-CoV-2)

##### Design

The present study was a clinical trial with a control group, with parallel, randomized groups, on 160 patients (40 patients in each group).

##### Settings and conduct

Sampling will be performed in Imam Reza Hospital and after obtaining informed consent from eligible patients, all of them were first matched in terms of the main clinical variable (pulmonary function test) and then randomly divided into groups 1- control, 2,3 and interventions. The treatment time is considered 14 days.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Hospitalized patients who are strongly suspected of having COVID 19 disease in terms of clinical findings and CT scan findings, and are clinically classified and hospitalized as severe, but have no organ damage, Confirmation of RT-PCR test for SARS-CoV-2, Age under 80 years, Confirmation of pneumonia by chest x-ray, Blood oxygen saturation below 93%, The relative stability of the cardiovascular status. Exclusion criteria: pregnant and lactating women, End-stage patients

##### Intervention groups

Control group: routine treatment based on physician's opinion and receiving 10 cc placebo syrup (made by Mashhad University of Medical Sciences) every 8 hours for 14 days Intervention group 1: routine treatment based on physician's opinion and receiving 10 cc opiucough syrup (made by Sepidaj Co.) Intervention group 2: routine treatment based on the doctor's opinion and receiving Noscatem (made by Temad Co.) syrup 10

cc Intervention group 3: routine treatment based on the doctor's opinion and receiving Noscough (made by FaranShimi Co.) syrup 10 cc

##### Main outcome variables

Recovery time, Hospital discharge, laboratory parameters

#### General information

##### Reason for update

Noscaough syrup and also the purity of Noscatem syrup (containing Noscapine alone) were included in the study.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180103038199N3**  
Registration date: **2020-08-30, 1399/06/09**  
Registration timing: **prospective**

Last update: **2021-01-27, 1399/11/08**

Update count: **3**

##### Registration date

2020-08-30, 1399/06/09

##### Registrant information

###### Name

Vahid Reza Askari

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3800 2264

###### Email address

askariv941@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

**Expected recruitment start date**

2020-10-22, 1399/08/01

**Expected recruitment end date**

2021-12-22, 1400/10/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation and comparison of the effectiveness of three herbal products containing Noscapine (Opiucough, Noscough and Noscatem) on clinical symptoms and para-clinical parameters in adults hospitalized with severe COVID-19

**Public title**

effects of three products containing Noscapine on COVID-19

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients who are strongly suspected of having COVID 19 disease in terms of clinical findings and CT scan findings  
Patients who are clinically classified and hospitalized as severe Patients who have no organ damage.  
Confirmation of RT-PCR test for SARS-CoV-2  
Age under 80 years  
confirmation of pneumonia by chest x-ray  
Blood oxygen saturation below 93%  
Relative stability of the cardiovascular status

**Exclusion criteria:**

Pregnant women Lactating women End stage patients

**Age**

To 80 years old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

No information

**Sample size**

Target sample size: 160

**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 160 samples. The bottles will be named including 40 bottles of syrup of control group (A) that have the same appearance as the intervention group, 40 bottles of syrup of intervention group 1 (B) that receive opiucough syrup, 40 bottles of syrup of intervention group 2 (C) that receive Noscatem syrup, 40 bottles of syrup of intervention group 3 (D) that receive Noscough syrup. Patients numbers from 000-040, 040-080 and 080-120, and 120-160 are considered for groups B, A, and C, and D respectively.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

**Street address**

Deputy of Research and Technology of the University, Qurashi Building, Next to Hoveyze Cinema, University Street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9138813944

**Approval date**

2020-05-23, 1399/03/03

**Ethics committee reference number**

IR.MUMS.REC.1399.283

**Health conditions studied****1****Description of health condition studied**

COVID-19

**ICD-10 code**

U07.1

**ICD-10 code description**

COVID-19

**Primary outcomes****1****Description**

Recovery time from the time of randomization of the studied patients to the improvement of clinical symptoms based on 7 common signs of improvement reported by the World Health Organization

**Timepoint**

before and 14 days after initiation of the intervention

**Method of measurement**

Relative criteria based on clinical symptoms as follows,  
1: not hospitalized with resumption to normal activities,  
2: not hospitalized but unable to resume normal activities,  
3: hospitalized without the need for oxygen therapy,  
4: hospitalized requiring supplemental oxygen,

5: hospitalized and need to receive high-speed oxygen from the nose or non-invasive ventilation or both, 6: hospitalized and need to receive oxygen using invasive ventilation or oxygen delivery from non-pulmonary routes or both, 7: death

## 2

### **Description**

Hospital discharge

### **Timepoint**

After initiation of the intervention

### **Method of measurement**

Duration of hospitalization

## **Secondary outcomes**

## 1

### **Description**

Blood level of alanine aminotransferase (ALT)

### **Timepoint**

Before and 14 days after initiation of the intervention

### **Method of measurement**

spectrometer

## 2

### **Description**

Blood urea nitrogen (BUN) level

### **Timepoint**

Before and 14 days after initiation of the intervention

### **Method of measurement**

spectrometer

## 3

### **Description**

Blood creatinine level

### **Timepoint**

Before and 14 days after initiation of the intervention

### **Method of measurement**

spectrometer

## 4

### **Description**

Blood level of aspartate aminotransferase (AST)

### **Timepoint**

Before and 14 days after initiation of the intervention

### **Method of measurement**

spectrometer

## 5

### **Description**

Red blood cell counts

### **Timepoint**

Before and 14 days after initiation of the intervention

### **Method of measurement**

Cell Counter

## 6

### **Description**

White blood cell counts

### **Timepoint**

Before and 14 days after initiation of the intervention

### **Method of measurement**

Cell Counter

## 7

### **Description**

Hemoglobin level

### **Timepoint**

Before and 14 days after initiation of the intervention

### **Method of measurement**

Autoanalyzer

## 8

### **Description**

Hematocrit level

### **Timepoint**

Before and 14 days after initiation of the intervention

### **Method of measurement**

Autoanalyzer

## 9

### **Description**

erythrocyte sedimentation rate

### **Timepoint**

Before and 14 days after initiation of the intervention

### **Method of measurement**

Wintrobe method

## 10

### **Description**

high-sensitivity C-reactive protein

### **Timepoint**

Before and 14 days after initiation of the intervention

### **Method of measurement**

ELISA kit

## **Intervention groups**

## 1

### **Description**

Control group: Routine treatment based on physician's opinion and receive placebo syrup (dextrous syrup 60% and edible color, made by Mashhad University of Medical Sciences) 10 cc every 8 hours for 14 days

### **Category**

Placebo

## 2

### **Description**

Intervention group1: Opiucough Syrup - Receive routine treatment and 10 cc of Opiucough syrup (containing 17 mg noscapine per 10 ml, commercially available, Sepidaj

Co.) every 8 hours for 14 days

**Category**

Treatment - Drugs

**3**

**Description**

Intervention group2: Noscatem Syrup - Receive routine treatment and 10 cc of Noscatem syrup (containing 17 mg noscapine per 10 ml, commercially available, Temad Co.) every 8 hours for 14 days

**Category**

Treatment - Drugs

**4**

**Description**

Intervention group3: Noscough Syrup - Receive routine treatment and 10 cc of Noscough syrup (containing 17 mg noscapine per 10 ml, commercially available, FaranSchimiCo.) every 8 hours for 14 days

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

22 Bahman Hospital, Neishabour

**Full name of responsible person**

Amir Beik Mohammadi

**Street address**

22 Bahman Hospital, Imam Ave.,

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Tafaghodi

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Deputy of Research and Technology of the University , Qurashi Building, Next to Hoveyzeh Cinema, University Street

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RIS@mums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Vahid Reza Askari

**Position**

PhD of clinical pharmacology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

School of Persian and Complementary Medicine, Ferdowsi complex, Vakil-Abad Blvd., Azadi Sq., Mashhad

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Vahid Reza Askari

**Position**

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**Other areas of specialty/work**

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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

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Vahid Reza Askari

**Position**

PhD of clinical pharmacology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**