

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the Effects of Noscopine on the Treatment of Cough in COVID-19 Outpatients

#### Protocol summary

##### Study aim

Determining the therapeutic effect of noscopine on cough in patients with COVID-19

##### Design

A controlled, parallel groups, randomized, double blinded and phase 3 clinical trial on 100 patients

##### Settings and conduct

The study is a double-blind randomized clinical trial. A total of 100 patients with mild COVID-19 referred to the corona clinic of Masih Daneshvari Hospital were randomly divided into two groups of 50 intervention and control.

##### Participants/Inclusion and exclusion criteria

Patients over 18 years of age with cough and positive RT-PCR for COVID-19 who are candidates for receiving outpatient remdesivir and the onset time is less than 5 days are included in the study. Pregnant, lactating, allergic patients to noscopine, morphine or any of the components of the formulation, history of seizures, diarrhea, diabetes and consumption of warfarin, benzodiazepines, opioid agonists and cough medicines are excluded.

##### Intervention groups

After obtaining informed consent, patients in the intervention group receive a syrup containing noscopine (Noscoug®) 20 cc every 6 hours for 5 days. Patients in the control group receive 7 cc diphenhydramine every 8 hours.

##### Main outcome variables

Response time to treatment; When the cough goes away; Cough intensity; Quality of Life; Blood oxygen level; Shortness of breath

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151227025726N31**

Registration date: **2022-06-18, 1401/03/28**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-06-18, 1401/03/28**

Update count: **0**

##### Registration date

2022-06-18, 1401/03/28

##### Registrant information

###### Name

Farzaneh Dastan

###### Name of organization / entity

Shahid Beheshti University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 912 270 5933

###### Email address

f\_dastan@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-06-18, 1401/03/28

##### Expected recruitment end date

2022-12-19, 1401/09/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the Effects of Noscopine on the Treatment of Cough in COVID-19 Outpatients

##### Public title

Evaluation of the Effects of Noscopine on the Treatment

of Patients with COVID-19

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

People over 18 years old Patient with cough and positive RT-PCR for COVID-19 and candidate for outpatient treatment The onset of illness equal to/less than 5 days

### Exclusion criteria:

Pregnancy Breastfeeding Allergy to noscapine, morphine or any of the components of the formulation History of seizure Diarrhea Diabetes Consumption of warfarin, benzodiazepines, opioid agonists Getting antitussive drugs

## Age

From **18 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Investigator
- Data analyser

## Sample size

Target sample size: **100**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Block randomization method was used in this study. Twenty five blocks including 4 patients generated with online website ([www.sealedenvelope.com/simple-randomiser/v1/lists](http://www.sealedenvelope.com/simple-randomiser/v1/lists)). In each block, 2 patients will be assigned to noscapine group and 2 patients will be assigned to control group.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Patients included to the study are randomized to two groups of drug and control (noscapine syrup and diphenhydramine syrup) by a randomizer (nurse) according to the randomization list taken from [www.sealedenvelope.com](http://www.sealedenvelope.com). The researcher and data analyst only receive the data in code and were not aware of patients' assignments to the two groups.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

Name of ethics committee

Ethics committees of School of Pharmacy, Nursing, and Midwifery; Shahid Beheshti University of Medic

#### Street address

No. 2660, Vali-e Asr St., Niyayesh Junction, Tehran

#### City

Tehran

#### Province

Tehran

#### Postal code

141556153

#### Approval date

2021-12-14, 1400/09/23

#### Ethics committee reference number

IR.SBMU.PHARMACY.REC.1400.252

## Health conditions studied

### 1

#### Description of health condition studied

COVID-19 pneumonia

#### ICD-10 code

U07.1

#### ICD-10 code description

COVID-19, virus identified

## Primary outcomes

### 1

#### Description

Time required to respond to treatment

#### Timepoint

Daily until discharge

#### Method of measurement

VAS scale

### 2

#### Description

Time required to resolve cough

#### Timepoint

Daily until discharge

#### Method of measurement

Patient history

### 3

#### Description

Intensity of cough

#### Timepoint

Daily until discharge

#### Method of measurement

CSS score

## Secondary outcomes

### 1

#### Description

Quality of Life

#### Timepoint

Before the start of the study and at the end of the study

**Method of measurement**

CQLQ questionnaire

**2**

**Description**

Blood oxygen level

**Timepoint**

Before the start of the study and at the end of the study

**Method of measurement**

Pulse oximeter

**3**

**Description**

Shortness of breath

**Timepoint**

Before the start of the study and at the end of the study

**Method of measurement**

Patient history

**Intervention groups**

**1**

**Description**

Intervention group: Patients receive Noscapine Syrup (Noscough®) 20 cc every 6 hours for 5 days.

**Category**

Treatment - Drugs

**2**

**Description**

Control group: Patients receive 7 cc diphenhydramine every 8 hours.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Masih Daneshvari Hospital

**Full name of responsible person**

Farzaneh Dastan

**Street address**

Masih Daneshvari Hospital, Shahid Bahonar Street (Niyavaran), Darabad.

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Tehran

**Province**

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f\_dastan@sbmu.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Afshin Zarghi

**Street address**

3rd floor, School of Medicine, Evin St, Shahid Chamran Highway

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1983963113

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mpd@sbmu.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Sahar Yousefian

**Position**

Hospital pharmacist

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Medical Pharmacy

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Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran

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saahar26@yahoo.com

## Person responsible for scientific inquiries

### Contact

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Assistant Professor  
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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
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Hospital pharmacist  
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**Other areas of specialty/work**  
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**Street address**  
Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran

**City**  
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Tehran  
**Postal code**  
19569-44413  
**Phone**  
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saahar26@yahoo.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

### Title and more details about the data/document

All potential data can be shared after blinding.

### When the data will become available and for how long

Six months after publishing the results

### To whom data/document is available

Researchers working in academic institutions

### Under which criteria data/document could be used

For research purposes and meta-analysis studies

### From where data/document is obtainable

Dr. farzaneh Dastan, Dr. Masih Daneshvari Hospital,  
Daar-Abad, Niavaran

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

Official letter to the researchers through Email  
(fzh.dastan@gmail.com)

### Comments