Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

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

Protocol summary

Study aim
Determining the therapeutic effect of noscapine 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 noscapine, 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 noscapine (Noscough®) 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

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Iran (Islamic Republic of)

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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 Noscapine on the Treatment of Cough in COVID-19 Outpatients

Public title
Evaluation of the Effects of Noscapine 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). 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. 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

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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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

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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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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