

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Dec 2023

Evaluation and comparison of the effectiveness of three herbal products containing Noscapipe (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 noscapipe (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 Noscapipe 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)

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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

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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

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22 Bahman Hospital, Imam Ave.,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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

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Full name of responsible person

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Latest degree

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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

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