Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Dec 2023

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 opioucough 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)

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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 160samples. 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 Hoveyzeh 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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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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School of Persian and Complementary Medicine, Ferdowsi complex, Vakil-Abad Blvd., Azadi Sq., Mashhad

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Person responsible for scientific inquiries

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Other areas of specialty/work

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Person responsible for updating data

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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