Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2021

Evaluating efficacy and safety of Stopcivir (Zataria multiflora Boiss+ Alium Sativum+ Heracleum persicum+ Satureja hortensis+ Dianthus+ Foeniculum vulgare+ opium) syrup on length of hospitalization in patients with COVID-19

Protocol summary

Study aim

The aim of this study was to investgate the effectiveness of Stop civir syrup consisting of Zataria multiflora Boiss, Alium Sativum, Heracleum persicum, Satureja hortensis, Dianthus, Foeniculum vulgare and a small amount of opium in patients with COVID-19.

Design

This study is a clinical trial with a control group, with parallel, double-blind, randomized, phase 3 groups on 150 patients. The Rand function of the Excel software was used for randomization.

Settings and conduct

This study will be performed in Imam Khomeini Hospital in Amol city and Firoozgar Hospital in Tehran. Patients are randomly assigned to be divided into two groups, treatment and non-treatment, according to the randomization block table (using software). To blind the study, the drugs are packaged in special envelopes with double-digit codes so that only the final evaluator, who is a physician, is aware of the type of medication that patients are receiving. Also, in order not to inform the patient, the placebo is given to the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The definitive case of covid 19 based on laboratory confirmation the probable diagnosis of covid 19 based on respiratory symptoms with radiological manifestations. Patients between 18-75 years Exclusion criteria: The presence of comorbidities Pregnancy and lactation History of allergies to herbal drugs Crisis and severe cases

Intervention groups

Treatment with Stopcivir: 75 patients will treat with the Stopcivir syrup for the first two days is10 cc every 4 hours and the next two days is 10 cc every 6 hours, with standard medications. Placebo: 75 patients will receive placebo for the first two days is10 cc every 4 hours and the next two days is 10 cc every 6 hours, with standard medications.

Main outcome variables

Length of hospitalization Shortness of breath Oxygen saturation

General information

Reason for update

Acronym

Stopcivir syrup

IRCT registration information

IRCT registration number: **IRCT20200411047016N1**
Registration date: **2020-05-31, 1399/03/11**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-31, 1399/03/11**
Update count: **0**

Registration date

2020-05-31, 1399/03/11

Registrant information

Name

Motahareh Rouhi Ardeshiri

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-05, 1399/01/17

Expected recruitment end date

2020-06-06, 1399/03/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating efficacy and safety of Stopcivir (Zataria multiflora Boiss+ Alium Sativum+ Heracleum persicum+ Satureja hortensis+ Dianthus+ Foeniculum vulgare+ opium) syrup on length of hospitalization in patients with COVID-19

Public title

The effect of Stopcivir syrup in patients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The definitive case of covid 19 based on laboratory confirmation Diagnosis of covid 19 based on CT or chest radiography Patients between 18-75 years

Exclusion criteria:

The presence of comorbidities (sever renal failure, sever liver failure, CHF, major cerebrovascular and cardiovascular disease, chronic lung disease, malignancy, immune system diseases including AIDS, encephalopathy) Pregnancy and lactation History of allergies to herbal drugs Crisis and severe cases

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be by blocking randomization (quadruple random blocks). Which is provided by statistical software. Randomization units are individuals. 150 outpatients referred to the hospital emergency department are randomly assigned to one of the two intervention and control groups. This study is a two-course method and patients in the intervention group will receive the intervention drug in addition to the routine treatment, but in the patient control group, they will receive the placebo along with the routine treatment.

Blinding (investigator's opinion)

Double blinded

Blinding description

To blind the study, the drugs are packaged with special tags with double-digit codes so that only the final evaluator, who is a physician, is aware of the type of medication that patients are receiving. Also, in order not to inform the patient, the placebo is given to the control group. Therefore, patients are not aware of the type of medication they are receiving.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Deputy of Research and Technology of Mazandaran University of Medical Sciences, Teacher Street, Teacher's Square

City

Sari

Province

Mazandaran

Postal code

48168-95474

Approval date

2020-04-05, 1399/01/17

Ethics committee reference number

IR.MAZUMS.REC.1399.061

Health conditions studied

1

Description of health condition studied

COVID- 19

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

Length of hospitalization

Timepoint

Hospitalization time and Hospital discharge time

Method of measurement

Check List

2

Description
Shortness of breath
Timepoint
Variable will be completed in the form of a checklist at the beginning of the Hospitalization and daily until the end of hospitalization.
Method of measurement
Check list

3

Description
Oxygen saturation
Timepoint
Variable will be completed in the form of a checklist at the beginning of the Hospitalization and daily until the end of hospitalization.
Method of measurement
Check list

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this study, the content of specific ratios of garlic, Lamiaceae, Heracleum persicum, Dianthus, Satureja hortensis plus a little opium in an alcohol-based solvent will be prepared and used as an adjunctive or concomitant medication alongside other routine medicine to treat patients with covid 19. Both groups will receive standard treatment. The dosage of the syrup for the first two days is 10 cc every 4 hours and the next two days is 10 cc every 6 hours, which is given to the patient by the ward nurse and is monitored.
Category
Treatment - Drugs

2

Description
Control group: The other group receives the placebo.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital, Amol city
Full name of responsible person
Seyde Sedighe Yousefi
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Center for Traditional Medicine and Complementary Medicine of Mazandaran University; Khazar Boulevard, Khazar Square of Sari
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Recruitment center
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Sponsors / Funding sources

1

Sponsor
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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
Mazandaran 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
Mazandaran University of Medical Sciences
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Position
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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