Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of therapeutic potential of Sinudrain HaftBahr solution in the treatment process of Covid 19 disease (clinical trial)

Protocol summary

Study aim
Determining the effectiveness of Haft Bahr Sinodrine product in the treatment of Covid 19

Design
60 patients referred to Shohada Tajrish Hospital in Tehran who meet the inclusion criteria are divided into two groups of intervention and control randomly based on the pair or individual patient admission code.

Settings and conduct
Intervention group: Group receiving Synodrine Haft Bahr solution (combination of 'Sainodrine' solution: The registered drug 'Synodrine Haft Bahr' has been registered with the registration number 0235-93S in the Ministry of Health of Iran under the name of Malabhar. The active ingredient of this drug is natural sodium chloride. And compounds from different salts such as calcium, chlorine, potassium, sodium). How to use Saino Drin Spray: 6 times a day in the nose, if patient has sputum in the back of the throat, should drain it and gargle three times a day after emptying the sputum. In case of any discharge, the discharge should be emptied. Control group: The group receiving the routine protocol of national treatment of patients with COVID 19 (Remdecivir) alone.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diagnosis based on clinical symptoms such as fever, cough, headache, runny nose and sometimes eyes, sore throat, shortness of breath, severe pain, dry mouth, loss of sense of smell, nausea and frequent vomiting. Exclusion criteria: reduction of arterial O2 blood pressure, severe pulmonary changes in radiography, lack of improvement in symptoms such as shortness of breath, nausea, and vomiting, and lack of improvement in the symptoms.

Intervention groups
Intervention group: national protocol includes Remdesivir for 5 days (two doses per day by injection) in addition to seven-sea sainodrine solution. Control group: only national protocol.

Main outcome variables
Blood oxygen levels, sore throat, length of hospital stay.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210914052471N1**
Registration date: **2021-10-01, 1400/07/09**
Registration timing: **prospective**

Last update: **2021-10-01, 1400/07/09**
Update count: **0**

Registration date
2021-10-01, 1400/07/09

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-10-12, 1400/07/20
Expected recruitment end date
2022-03-20, 1400/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of therapeutic potential of Sinudrain HaftBahr solution in the treatment process of Covid 19 disease (clinical trial)

Public title
Clinical trial of Sinudrain HaftBahr solution
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Individuals with positive PCR test Covid19 Blood oxygen levels above 80 Age between 17 and 65 years Pulmonary involvement less than 40% Patients who do not need to use a ventilator
Exclusion criteria:
History of uncontrolled hypertension
Age
From **17 years** old to **70 years** old
Gender
Both

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **1**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is done simply based on the patients' hospital admission code. The even codes will be in the intervention group and the odd codes will be in the control group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahid Beheshti University of Medical Sciences
Street address
Tajrish
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Province
Tehran
Postal code
2545268565
Approval date
2021-03-10, 1399/12/20
Ethics committee reference number
IR.SBMU.RETECH.REC.1399.1209

Health conditions studied

1

Description of health condition studied
Covid 19
ICD-10 code
U07.1
ICD-10 code description
Covid-19, virus identified

Primary outcomes

1

Description
SPO2
Timepoint
Daily
Method of measurement
Using a pulse oximeter

2

Description
Feeling of tightness in the throat
Timepoint
Daily
Method of measurement
Patient history

Secondary outcomes

1

Description
Duration of patient treatment time
Timepoint
End of clinical symptoms
Method of measurement
questionnaire

Intervention groups

1

Description
Intervention group: In this group, the treatment regimen is in the form of routine protocol (RamedSavier two injectable doses for 5 days) + the drug Synodrine Haft Bahr. Iranian medical treatment and education has been

registered under the name of Ma'l-Bahr and has been added to the list of natural products of traditional Iranian medicine. It is in the form of 30 cc spray and a solution containing 240 cc in a bottle. The active ingredient is natural sodium chloride and compounds of different salts such as calcium, chlorine, potassium, sodium. Patients are taught how to use it before consumption. How to use: If you run out of 30 ml of spray contents, pour 240 ml of the contents of the bottle into a 30 ml spray bottle and consume it, and according to the instructions, 3 puffs in each nostril six times a day, and sputum out of the mouth. And remove the nose. Also pour a little of the above solution in the throat and gargle 3 times a day. The duration of use is 5 days. If the patient needs complementary drugs such as vitamins, it is not forbidden to prescribe and can be used in both control and intervention groups.

Category

Treatment - Drugs

2

Description

Control group: In this group, the treatment regimen in the form of using a routine protocol (Ramsavior two injectable doses for 5 days) is not contraindicated if the patient needs adjuvant drugs such as vitamins, and can be used in both control and intervention groups.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tehran Tajrish Martyrs Hospital
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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
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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All available data can be provided by identifying the author's name

When the data will become available and for how long
Access starts three months after the article is published

To whom data/document is available
All academic institutions

Under which criteria data/document could be used
In order to inform people with limited data analysis and use it in similar articles

From where data/document is obtainable
Hamid Chegni should send a request via email

What processes are involved for a request to access data/document
Will be emailed within one week of request

Comments