# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

31 May 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**

**Name**
Hamid Chegni

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 21 2270 7346

**Email address**
h.chegini2010@yahoo.com

**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
**City**
Tehran
**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
**Full name of responsible person**
Hamid Chegni
**Street address**
Tajrish
**City**
Tehran
**Province**
Tehran
**Postal code**
12568569885
**Phone**
+98 21 2254 8755
**Email**
h.chegini2010@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Hamid Cchegni
**Street address**
Tajrish
**City**
Tehran
**Province**
Tehran
**Postal code**
2542546854
**Phone**
+98 21 2254 5685
**Email**
h.chegini@sbmu.ac.ir
**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**
Hamid Chegni
**Position**
Associate professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Immunology
**Street address**
Tajrish
**City**
Tehran
**Province**
Tehran
**Postal code**
2545236585
**Phone**
+98 21 2258 4586
**Email**
h.chegini2010@yahoo.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**
Hamid Chegni

**Position**
Associate professo

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Immunology

**Street address**
Tajrish

**City**
Tehran

**Province**
Tehran

**Postal code**
2545254856

**Phone**
+98 21 2254 5875

**Email**
h.chegini2010@yahoo.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Shahid Beheshti University of Medical Sciences

**Full name of responsible person**
Hamid Chegni

**Position**
Associate professor

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Immunology

**Street address**
Tajrish

**City**
Tehran

**Province**
Tehran

**Postal code**
2548568596

**Phone**
0212254857586

**Email**
h.chegini20102@yahoo.com

## 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**