# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

13 Nov 2026

## Comparison of the therapeutic effect of Sofosbuvir with Control group in outpatients with Covid-19 referred to outpatient clinics in Ahvaz

### Protocol summary

**Study aim**

To evaluate whether (Sofosbuvir ) increases significant clinical improvement as compared to standard of care in out patients patients with mild COVID-19

**Design**

This is a parallel 2-arm randomized, controlled, double-blind, multi center study. 360 patients are enrolled and followed for 14 days

**Settings and conduct**

This study will be performed in outpatient medical centers in Ahvaz by researchers from the Lung Diseases Research Institute. Physicians who evaluate results and statistics that analyze data become blind, and patients and physicians who treat patients do not know the specific treatment group.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Outpatients with positive PCR and mild clinical signs without pulmonary involvement on CT scan. (As defined by patient with sore throat, dry cough ±, loss of sense of smell and taste, body aches, nausea and vomiting, O2 Sat ≥ 95, T <38, RR <24, stable pulse and blood pressure). Exclusion criteria: 18y> age, transplant patients, severe skin history including TEN or Steven Johnson, allergy or allergy to the drug Male study, the patient has previously been treated with this drug for other reasons (hepatitis C, etc.) , Is not able to take pills, is not aware of his condition, is deficient in G6PD enzyme, is being treated with anticonvulsant drugs, has fever and respiratory symptoms for 2 weeks, is being treated with immunosuppressive drugs, 1 month ago drugs Has received antiviral for Covid-19, is pregnant or lactating, has ESRD, Advance CKD (liver, lung, heart, hematology) and solid tumors and cancers of neurological diseases such as CVA, etc., are excluded.

**Intervention groups**

360ligible patients with mild COVID-19 in a 1:1 ratio: • Standard of care treatment • tablet (Sofosbuvir 400mg) + Standard of care treatment

**Main outcome variables**

Clinical recovery (composite) within 14 days

### General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20201127049505N1**
Registration date: **2021-02-06, 1399/11/18**
Registration timing: **retrospective**

Last update: **2021-02-06, 1399/11/18**
Update count: **0**

**Registration date**

2021-02-06, 1399/11/18

**Registrant information**

**Name**

mahtab moinpoor

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 61 3322 1251

**Email address**

mahtab_moinpoor@yahoo.com

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2020-12-28, 1399/10/08

**Expected recruitment end date**

2021-01-11, 1399/10/22

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**
Comparison of the therapeutic effect of Sofosbuvir with Control group in outpatients with Covid-19 referred to outpatient clinics in Ahvaz

**Public title**
Study on the evaluation of the safety and efficacy of Sofosbuvir in participants with mild coronavirus in outpatients (COVID-19)

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Outpatients presented with positive PCR and mild clinical signs without pulmonary involvement on CT scan As defined by patient with sore throat dry cough loss of sense of smell and taste nausea and vomiting O2 Sat ≥ 95 T <38 RR <24 stable pulse and blood pressure body aches

**Exclusion criteria:**
y>18 Organ transplant Severe skin history including TEN or Steven JohnsonAllergy to the studied drug The patient has previously been treated with this drug for other reasons Hepatitis C Not able to take pills Lack of awareness Be treated with anticonvulsant drugs Have fever and respiratory symptoms from 2 weeks ago Be treated with immunosuppressive drugs Be pregnant or breastfeeding 1 month ago received antiviral drugs for Covid-19 ESRD Advance CKD Advance liver disease Pulmonary Advance Disease Cardiac Advance Disease Advance Disease Hematology Solid tumor Cancer of neurological diseases such as CVA your situationG6PD deficient Be pregnant or breastfeeding

**Age**
From **18 years** old

**Gender**
Both

**Phase**
3

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **360**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
The nature of assigning patients to each of the two study groups was a randomized block method in which a 6-item block was used according to 60 6-item blocks. A: S B: c . In this way, patients are not aware of the treatment assigned to them. Also, the person evaluating the outcome of the treatment is kept unaware of the type of treatment. Blinding then Allocate Allocation In order to minimize the bias in the study, the Allocate method will be used. This will be done using unique codes or Uniqe code. In such a way that each person is assigned a three-digit number at random.

**Blinding (investigator's opinion)**
Single blinded

**Blinding description**
The task of treatment will remain unknown until the patient is random. Physicians who treat patients will remain blind. Physicians who evaluate results and statistics that analyze data will all become blind.

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics Committee of Ahwaz University of Medical Sciences

**Street address**
Imam Khomeini Hospital, 24 meters from the first floor of the office of the Department of Internal Education

**City**
ahwaz

**Province**
Khouzestan

**Postal code**
6193673116

**Approval date**
2020-12-23, 1399/10/03

**Ethics committee reference number**
IR.AJUMS.REC.1399.754

## 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**
Shortness of breath

**Timepoint**
day 14 or sooner at the discretion of the physician

**Method of measurement**
Clinical evaluation

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group:400mg of Sofosbovir and Vitamin B1300 control group
**Category**
Treatment - Drugs

### 2

**Description**
Control group: Vitamin B1300
**Category**
Placebo

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Shafa Hospital
**Full name of responsible person**
Maryam Haddadzadeh Shoushtari
**Street address**
Imam Khomeini Hospital, 24 meters from the first floor of the office of the Department of Internal Education
**City**
Ahwaz
**Province**
Khouzestan
**Postal code**
6193673116
**Phone**
+98 61 3322 1251
**Email**
drmahtab.moeinpour@yahoo.com

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Ahvaz University of Medical Sciences
**Full name of responsible person**
Mohammad Badavi Zade
**Street address**
Imam Khomeini Hospital, 24 meters from the first floor of the office of the Department of Internal Education
**City**
Ahwaz
**Province**
Khouzestan
**Postal code**
6193673116
**Phone**
+98 61 3322 1251
**Email**
Drmahtab.moeinpour@yahoo.com
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
No
**Title of funding source**
not has
**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**
Ahvaz University of Medical Sciences
**Full name of responsible person**
Maryam Hadad Zade Shoushtary
**Position**
Consultant
**Latest degree**
Specialist
**Other areas of specialty/work**
Internal Medicine
**Street address**
Imam Khomeini Hospital, 24 meters from the first floor of the office of the Department of Internal Education
**City**
Ahwaz
**Province**
Khouzestan
**Postal code**
6193673116
**Phone**
+98 21 3322 1251
**Email**
Drmahtab.moeinpour@yahoo.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Ahvaz University of Medical Sciences
**Full name of responsible person**
Maryam Haddadzadeh Shoushtari
**Position**
Consultant
**Latest degree**
Specialist
**Other areas of specialty/work**

Internal Medicine

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**Email**

Drmahtab.moeinpour@yahoo.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Maryam Haddadzadeh Shoushtari

**Position**

Consultant

**Latest degree**

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**Other areas of specialty/work**

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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**

Yes - There is 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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

The individual data of the participants in the study of all potential data can be shared after the identifiable individuals

**When the data will become available and for how long**

Access period starts from 1400

**To whom data/document is available**

The data will be available only to researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

Only SPSS data will be available.

**From where data/document is obtainable**

09133583977

**What processes are involved for a request to access data/document**

not

**Comments**