Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 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
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Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

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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