Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

the efficacy of Interferon beta 1 a (ReciGen) in treatment of patients with Covid-19 in Sina Hospital Emergency Department

Protocol summary

Study aim
1. comparing Recigen and placebo in the reduction of dyspnea in covid 19 patients 2. comparing Recigen and placebo in the reduction of cough in covid 19 patients 3. comparing Recigen and placebo in the reduction of hypoxia in covid 19 patients 4. comparing Recigen and placebo in the reduction of fever in covid 19 patients 5. comparing Recigen and placebo in the reduction of hospital stay and discharge rate in covid 19 patients

Design
this is a two arm parallel group triple blinded placebo controlled randomized clinical trial on 40 patients. based on the random sequence, the patients will assign to either group A or B, and they will receive 1 daily dose (44 mcg) of Recigen or placebo subcutaneously for five days or until the discharge day (each came sooner).

Settings and conduct
in this study, the patient, the researcher, the supervisor clinician and the statistician in blinded about the placebo and recigen groups. the location is Sina Hospital, Tehran University of Medical Sciences

Participants/Inclusion and exclusion criteria
inclusion criteria: diagnosis of covid 19 based on CT scan findings and being admitted based on the ministry of health guidelines 1. pregnancy 2. breastfeeding 3. do not consent to participate in the study 4. allergies to the drugs 5. not having proper phone number for follow ups

Intervention groups
based on the assigned group A or B, the patient will receive 1 daily dose (44 mcg) of Recigen or placebo subcutaneously for five days or until the discharge day (each came sooner).

Main outcome variables
hospital stay days; need for ICU admission; need for intubation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150914024017N1**
Registration date: **2020-04-03, 1399/01/15**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-03, 1399/01/15**
Update count: **0**

Registration date
2020-04-03, 1399/01/15

Registrant information

Name
Pooya Payandemehr

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 6312 1413

Email address
p-payandemehr@sina.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-27, 1399/01/08

Expected recruitment end date
2021-02-19, 1399/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
the efficacy of Interferon beta 1 a (ReciGen) in treatment of patients with Covid-19 in Sina Hospital Emergency

Department

Public title
ReciGen for treatment of Covid-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients who are diagnosed to have covid-19 based on Chest Ct Scan patients being admitted to emergency room based on local guidelines age 18 years or loder
Exclusion criteria:
pregnancy breast feeding do not consent to be in this study allergies to interferon not having a proper phone number for follow up calls
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
a random sequence was generated by "random.org" , in which every subject in the study from number 1 to 40, is randomly assigned to one of the treatment groups A or B. based on this random sequence, patient 1 and 2 will be assigned to group A and patient number 3 will be assigned to other group and this goes on until 40 patients enroll in the study.
Blinding (investigator's opinion)
Triple blinded
Blinding description
the hospital pharmacist puts Recigen and Placebo (which produced by the same company and is exactly similar to Recigen without the active ingredient) in Groups A and B. he is the only person who knows which group has Recigen and which one has the placebo. the researcher injects the drug to the patients based on the randomization chart in which each patient is assigned to groups A and B. The patient, the researcher, the clinicians who supervise the patient treatment and the statistician who analyses the data will not know which group received placebo and which one received Recigen.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethics committee, Vice-Chancellor in Research Affairs-Tehran University of Medical Sciences
Street address
Imam Khomeini ave, Hasan abad sq, Sina Hospital
City
Tehran
Province
Tehran
Postal code
1136746911
Approval date
2020-03-23, 1399/01/04
Ethics committee reference number
IR.TUMS.VCR.REC.1399.026

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
hospital stay
Timepoint
discharge date
Method of measurement
checklist

2

Description
need for ICU admission
Timepoint
discharge date
Method of measurement
check list based on treating clinicians judgment

3

Description
need for intubation
Timepoint
discharge date

Method of measurement
check list based on treating clinicians judgment

Secondary outcomes

1

Description
O2 saturation
Timepoint
daily
Method of measurement
pulse oxymeter

2

Description
fever
Timepoint
daily
Method of measurement
thermometer

3

Description
side effects
Timepoint
daily
Method of measurement
check list based on treating clinicians judgment

Intervention groups

1

Description
Intervention group: subcutaneous injection of Recigen (44mcg) daily until 5 days or the discharge day (which ever come sooner) in addition to standard treatment (based on the Ministry of Health protocol: chloroquine, etc ..)
Category
Treatment - Drugs

2

Description
Control group: subcutaneous injection of placebo daily until 5 days or the discharge day (which ever come sooner) in addition to standard treatment (based on the Ministry of Health protocol: chloroquine, etc ..)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Pooya Payandemehr
Street address
Imam Khomeini ave., Hasan Abad sq., Sina Hospital
City
Tehran
Province
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1136746911
Phone
+98 21 6312 1413
Email
p-payandemehr@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohamad Ali Sahraian
Street address
Keshavarz Blvd., Qods Ave., Tehran University of Medical Sciences
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1417653761
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+98 21 6649 2271
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p-payandemehr@sina.tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person

Pooya Payandemehr

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Emergency Medicine

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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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
All data, protocols and reports will publish in reputable journals after statisticalanalysis

When the data will become available and for how long
Oct2020- April 2021

To whom data/document is available
no limitation

Under which criteria data/document could be used
to find a solution and treat patient who infected with new corona virus.

From where data/document is obtainable
corresponding author

What processes are involved for a request to access data/document
all data would be public and if any questions raised, it is possible to ask from corresponding author

Comments