

# 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 older

**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

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Imam Khomeini ave., Hasan Abad sq., Sina Hospital

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**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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**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  
**Street address**  
Imam Khomeini Ave., Hasan Abad Sq., Sina Hospital  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**

Pooya Payandemehr  
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Assistant Professor  
**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

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 statistical analysis

### 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