

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of low dose whole lung irradiation for treatment of resistant COVID-19 pneumonia

#### Protocol summary

##### Study aim

Evaluation of low dose whole lung irradiation for treatment of resistant COVID-19 pneumonia

##### Design

Single arm, phase 2 clinical trial on 10 volunteer patients

##### Settings and conduct

Treatment of patients will be conducted in the radiotherapy department of Imam Khomeini Hospital Complex Cancer Institute, and radiation treatment planning will be done by study supervisor. In order to prevent risks of disease spread, treatment will be given on the last working shifts of radiation oncology department on Wednesday evening and Thursday morning, and all treatment environment will be disinfected according to standard guidelines for patient accrual on Saturday.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: male patients older than 60, diagnosis of COVID-19 based on PCR or imaging, clinical symptoms of pneumonia or Acute Respiratory Distress Syndrome (coughing, dyspnea, need for supplemental oxygen), obvious COVID-19 pulmonary patterns on chest CT, severe or refractory lung disease, written informed consent  
Exclusion criteria: intubation, need for continuous non-invasive ventilation (NIV), continuous positive airway pressure (CPAP), or lung disease explainable by other etiologies.

##### Intervention groups

Intervention group: Patients will receive low dose whole lung irradiation of 100 Rads with 6 megavoltage photons in a single fraction through anteroposterior and posteroanterior fields with Varian linear accelerator radiotherapy device.

##### Main outcome variables

Vital signs, length of hospital stay, CT score, death

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170211032494N3**  
Registration date: **2020-05-25, 1399/03/05**  
Registration timing: **prospective**

Last update: **2020-05-25, 1399/03/05**

Update count: **0**

##### Registration date

2020-05-25, 1399/03/05

##### Registrant information

##### Name

Nima Mousavi Darzikolaee

##### Name of organization / entity

Radiation Oncology Research Center, Cancer Institute, Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6694 0945

##### Email address

mousavi-n@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-27, 1399/03/07

##### Expected recruitment end date

2020-06-04, 1399/03/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of low dose whole lung irradiation for

treatment of resistant COVID-19 pneumonia

**Public title**

Low dose whole lung irradiation for treatment of COVID-19 pneumonia

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Diagnosis of COVID-19 by PCR or imaging Clinical symptoms of pneumonia or Acute Respiratory Distress Syndrome (coughing, dyspnea, need for supplemental oxygen) Obvious COVID-19 pulmonary patterns in chest CT scan Age over 60 Male gender Severe/refractory lung disease associated with COVID-19 Completion of written informed consent

**Exclusion criteria:**

Intubation Need for continuous NIV (Non-Invasive Ventilation) Need for CPAP (Continuous Positive Airway Pressure) Pulmonary disease due to non-COVID etiologies

**Age**

From **60 years** old

**Gender**

Male

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **10**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features**

In order to prevent the risks of disease spread, treatment will be taken on the last working shift of radiation oncology department on Wednesday evening and Thursday morning, when no other patient or personnel is in the working place. After the treatment session, all the treatment environment and its vicinity will be disinfected according to the standard guidelines for the next working shift on Saturday.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical

Sciences

**Street address**

6th floor, Vice Chancellor in Research Affairs, Central department of Tehran University of Medical Sciences, Qods Ave, Keshavarz Blvd

**City**

Tehran

**Province**

Tehran

**Postal code**

1417653761

**Approval date**

2020-05-13, 1399/02/24

**Ethics committee reference number**

IR.TUMS.VCR.REC.1399.362

**Health conditions studied****1****Description of health condition studied**

COVID-19 pneumonia

**ICD-10 code**

U07.1

**ICD-10 code description**

COVID-19, virus identified

**Primary outcomes****1****Description**

Blood pressure

**Timepoint**

Before intervention and every 6 hours after intervention

**Method of measurement**

Sphygmomanometer

**2****Description**

Length of hospital stay

**Timepoint**

discharge date

**Method of measurement**

discharge date minus admission dates

**3****Description**

CT score

**Timepoint**

5 days after intervention

**Method of measurement**

Scores will range from 0-5 based on each lung lobe's percentile involvement as 0 for non-involvement, 1 for less than 5% involvement, 2 for 5-24% involvement, 3 for 25-49% involvement, 4 for 50-74% involvement and, 5 for 75-100% involvement, and the sum of each lobe score will be compared between the initial CT and the CT scan performed after discharge.

## 4

### **Description**

Death

### **Timepoint**

Until discharge

### **Method of measurement**

Death verification

## 5

### **Description**

Pulse Rate

### **Timepoint**

Before intervention and every 6 hours after intervention

### **Method of measurement**

Pulse Oxymeter

## 6

### **Description**

Respiratory rate

### **Timepoint**

Before intervention and every 6 hours after intervention

### **Method of measurement**

Counting in one minute by physician

## 7

### **Description**

Body temperature

### **Timepoint**

Before intervention and every 6 hours after intervention

### **Method of measurement**

Thermometer

## 8

### **Description**

Oxygen saturation

### **Timepoint**

Before intervention and every 6 hours after intervention

### **Method of measurement**

Pulse oxymeter

## **Secondary outcomes**

## 1

### **Description**

SARS-CoV-2 Viral Load

### **Timepoint**

Before the intervention and 4 days after the intervention

### **Method of measurement**

SARS-CoV-2 Plasma PCR

## 2

### **Description**

Interleukin-6

### **Timepoint**

Before the intervention and 48 hours after the intervention

## **Method of measurement**

Interleukin-6 quantitative ELISA

## 3

### **Description**

Interleukin-1

### **Timepoint**

Before the intervention and 48 hours after the intervention

### **Method of measurement**

Interleukin-1 quantitative ELISA

## **Intervention groups**

## 1

### **Description**

Intervention group: All patients will receive low dose whole lung irradiation for 100 Rads with 6 megavoltage photon beams in one session through two anteroposterior and posteroanterior fields by Varian linear accelerator radiotherapy device

### **Category**

Treatment - Other

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Imam Khomeini Hospital Complex

#### **Full name of responsible person**

Nima Mousavi Darzikolaee

#### **Street address**

Imam Khomeini Hospital Complex, Keshavarz Boulevard, Tehran

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

1419733141

#### **Phone**

+98 21 6694 8679

#### **Email**

mousavi-n@razi.tums.ac.ir

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Tehran University of Medical Sciences

#### **Full name of responsible person**

Dr. Mohammad Ali Sahraian

#### **Street address**

6th floor, Vice Chancellor in Research Affairs, Central department of Tehran University of Medical Sciences, Qods Ave, Keshavarz Blvd

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Tehran

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Tehran

**Postal code**

1417653761

**Phone**

+98 21 8163 3685

**Email**

vcr@tums.ac.ir

**Web page address**<http://vcr.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**

Nima Mousavi Darzikolaee

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Radiotherapy

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Imam Khomeini Hospital Complex, Keshavarz Boulevard, Tehran

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**Person responsible for updating data****Contact****Name of organization / entity**

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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**

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**

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**

All collected Individual Participant Data (IPD) will be shareable after being anonymized

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

Document files will become available indefinitely 2 months after publication of the results

**To whom data/document is available**

Researchers of academic institutions will be given access to the required data.

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

All types of analysis are permitted. All acquired data will be shareable if the requester is identified as an academic researcher by the study supervisor.

**From where data/document is obtainable**

Data will be accessible through Dr Nima Mousavi Darzikolaee; Email: Mousavi.nima@yahoo.com/ mousavin@razi.tums.ac.ir

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

The applicants should send an email to the provided email addresses indicating their scientific and academic identity, and declare where they will be using this data and for what intention, and state that their published work will cite the relevant researchers. In this case they will be able to obtain the relevant data files.

**Comments**