

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

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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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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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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Nima Mousavi Darzikolaee

Position

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Latest degree

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Other areas of specialty/work

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

Tehran University of Medical Sciences

Full name of responsible person

Nima Mousavi Darzikolaee

Position

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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