Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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1419733141
Phone
+98 21 6694 8679
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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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+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
Street address
Imam Khomeini Hospital Complex, Keshavarz Boulevard, Tehran
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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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

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Other areas of specialty/work
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1419733141
Phone
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Email
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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/ mousavi-n@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