Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Assessment of adding low dose pulmonary radiotherapy to the national protocol of COVID-19 management: A pilot trial.

Protocol summary

Study aim
All
Design
Phase 1-2 clinical study of feasibility and safety of 0.5 Gy radiotherapy to both lungs on moderate to severe cases of COVID-19 pneumonia
Settings and conduct
Patients are selected in multi- disciplinary team and will receive low dose RT in Imam Hossein Hospital in conjunction with standard treatment. The clinical course and biochemical parameters of inflammation are carefully monitored for 28 days post treatment.
Participants/Inclusion and exclusion criteria
Confirmed COVID-19 diagnosis (PCR or serologic) Presence of pulmonary involvement (defined by P/F ratio or NIV need) Less than 3 days since the onset of ARDS Age > 60 years
Intervention groups
all patients due to inclusion criteria receive standard national protocol of COVID-19 treatment plus low dose radiotherapy to both lungs.
Main outcome variables
Change in clinical condition: ICU stay Hospital stay Intubation / Extubation event Change in pulmonary functions: P/F ratio PaO2 Change in radiologic findings: CXR Chest CT Change in serum inflammation markers: IL-6 CRP

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200509047366N1**
Registration date: **2020-05-12, 1399/02/23**
Registration timing: **prospective**

Last update: **2020-05-12, 1399/02/23**
Update count: **0**
Registration date
2020-05-12, 1399/02/23

Registrant information
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-05-21, 1399/03/01
Expected recruitment end date
2020-07-22, 1399/05/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessment of adding low dose pulmonary radiotherapy to the national protocol of COVID-19 management: A pilot trial.

Public title
Radiotherapy in COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Confirmed COVID-19 diagnosis (PCR or serologic)

Presence of pulmonary involvement (defined by P/F ratio or NIV need) Less than 3 days since the onset of ARDS Age > 60 years ↑ IL-6 (if available) ↑ CRP

Exclusion criteria:

Lack of informed consent Inability to transfer to the radiation unit Hemodynamic instability Septic shock and organ dysfunction Severe ARDS P/F ratio ≤ 100 mmHg History of cardiac failure Contraindications to radiation

Age

From **60 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **5**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Vice-Chancellor in Research Affairs - Shahid Beheshti University of Medical Scie

Street address

Madani St

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1979833361

Approval date

2020-05-03, 1399/02/14

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.073

Health conditions studied

1

Description of health condition studied

COVID-19 pneumonia

ICD-10 code

J12.81

ICD-10 code description

Pneumonia due to SARS-associated coronavirus

Primary outcomes

1

Description

Increase in arterial oxygen pressure

Timepoint

day 1,2,3,4,5,6,7,14,21,28 post treatment

Method of measurement

Blood sample

Secondary outcomes

1

Description

P/F ratio

Timepoint

day 1,2,3,4,5,6,7,21,28

Method of measurement

Blood gas analysis

2

Description

hs-CRP

Timepoint

day 1,2,3,4,5,6,7,21,28

Method of measurement

blood sample

3

Description

IL-6 serum level

Timepoint

day 1,4,7,21,28

Method of measurement

blood sample

4

Description

ESR

Timepoint

day 1,2,3,4,5,6,7,14,21,28

Method of measurement

Blood sample

Intervention groups

1

Description

Intervention group: Low dose RT

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Immam Hossein Hospital
Full name of responsible person
Ahmad Ameri
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Web page address
https://www.sbu.ac.ir/adj/RESVP/Pages/default.aspx

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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Position
Resident
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available