

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

Name

Nazanin Rahnama

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2273 1056

Email address

nazanin.rahnama@sbm.ac.ir

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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Postal code

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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Madani St.,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
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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
Nazanin Rahnama

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Radiation Oncology

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Other areas of specialty/work

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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