

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 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 PaO<sub>2</sub>  
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

**City**

Tehran

**Province**

Tehran

**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

**Street address**

Madani St.,

**City**

Tehran

**Province**

Tehran

**Postal code**

1979833361

**Phone**

+98 21 7343 0000

**Email**

a\_ameri@sbmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Rezaei Tavirani

**Street address**

daneshjoo Blvd, Yemen St.,

**City**

Tehran

**Province**

Tehran

**Postal code**

1979833361

**Phone**

+98 21 2243 1920

**Email**

publicrelations@sbmu.ac.ir

**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

**Street address**

No 48, Golesang Alley, Niyavaran Ave, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1979833361

**Phone**

+98 21 2273 1056

**Fax****Email**

Nazanin.rahnama@sbmu.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Ahmad Ameri

**Position**

Professor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Radiotherapy

**Street address**

Madani St.,

**City**

Tehran

**Province**

Tehran

**Postal code**

1979833361

**Phone**

+98 912 308 8087

**Email**

a\_ameri@sbmu.ac.ir

## Person responsible for updating data

#### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Rahnama

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Radiotherapy

**Street address**

نياوران، خ آيت الله محمودي يك، پلاك ٤٨ مجتمع مسكوني گلستنگ

**City**

تهران

**Province**

Tehran

**Postal code**

1979833361

**Phone**

+98 912 315 7370

**Fax**

**Email**

Naz.rahnama@gmail.com

**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