Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jul 2026

Comparative study of the effectiveness of low-dose lung radiation in comparison with placebo in the treatment of cancer patients with severe inflammatory phase of covid19 pneumonia

Protocol summary

Study aim

Comparison of the effectiveness of low-dose lung radiotherapy compared with placebo in the treatment of the sever phase of the inflammatory phase of Covid-19 pneumonia

Design

Clinical trial with control group, double-blind, randomized, on 36 patients. Spss20 software was used for randomization.

Settings and conduct

This double-blind study is performed on cancer patients who are currently in the severe inflammatory phase of Covid-19 pneumonia and are hospitalized in Omid Hospital in Isfahan. Patients in both groups will receive treatments based on the Covid-19 treatment protocol. Patients in the intervention group will receive pulmonary radiotherapy at a dose of 5 Gy in one fraction. Then the extent of lung involvement and the level of inflammatory factors and the hospitalization duration in both groups will be compared. In this study, patients, researchers and statistical analysts will be blinded and unaware of the placement of individuals in intervention or control groups.

Participants/Inclusion and exclusion criteria

Inclusion: Adult patients with underlying cancer who are currently in the severe inflammatory phase of Covid-19 pneumonia. exclusion: Patients who for any reason have contraindications to chest radiotherapy or are receiving radiotherapy treatment in this area.

Intervention groups

intervention group will undergo contouring of lungs and vital organs after performing CT simulation. They will undergo a single radiation fraction to both lungs at a dose of 5 Gy. positioning and adjusting the device for Patients in the control group will be similar to the intervention group, and instead of receiving radiation, laser light will be used for them. The duration of receiving radiation, as well as all measures related to setting the device will be the same in both groups.

Main outcome variables

Duration of hospitalization ; Lung involvement; reduction of inflammatory factors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201203049585N2**
Registration date: **2021-09-21, 1400/06/30**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-21, 1400/06/30**
Update count: **0**

Registration date

2021-09-21, 1400/06/30

Registrant information

Name

Nadia Najafizade

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3775 2366

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-05, 1400/06/14

Expected recruitment end date

2022-02-03, 1400/11/14

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of the effectiveness of low-dose lung radiation in comparison with placebo in the treatment of cancer patients with severe inflammatory phase of covid19 pneumonia

Public title
Evaluation of the effect of low-dose lung radiotherapy in the treatment of Covid 19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Over 18 years Having cancer Covid-19 pneumonia that has been confirmed by PCR test Lung involvement more than 50% that has been confirmed by HRCT Interleukin-6 ≥ 40 or establishing two of the following criteria: D-dimmer ≥ 1000 CRP ≥ 100 LDH ≥ 300 Ferritin ≥ 500 Not a candidate for ICU admission
Exclusion criteria:
Any contraindication for radiotherapy Current chest radiotherapy Active pulmonary metastasis A history of previous lung radiotherapy Being pregnant The patient's WBC be less than 1000 in the day before the intervention Unable to understand the conditions of the intervention, in the terms of mental health
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
All patients wishing to participate in the study will be randomly divided into two groups A and B using SPSS20 software.To perform randomization by SPSS software, the "Data" option is selected from the SPSS software toolbar, then in the new window, the "Select cases" option is selected, then in the "Select" box, the "Random sample of cases" option is selected, and then the "Sample" option is selected. Then, in the new window, the "Exactly" option is selected and the number of patients in each group and the total number of samples are entered in the empty boxes, respectively (in this study, 18 and 36, respectively). Then the" Continue" and "Ok" options are selected and finally the randomly generated variables are randomly divided into two equal groups with codes 0 and 1 in the Data View page, which is conventionally assigned code 1 to the intervention group and code 0 to the control group. Patients will be randomly assigned to intervention or control groups by someone other than the lead researcher and statistical analyst.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is performed by double-blind method. Patients participating in the study will be explained that they may be in one of two groups of doing radiotherapy or not doing radiotherapy. The process of radiotherapy, including patient and device setup, will be performed similarly for both groups, and whether or not radiation is received will be based on the patients' position in the intervention or control group. During the study process, participants, researchers, evaluators and Analyst will not know how people are positioned in the groups, and this information will be kept during the study and until the end of study, by coordinator of the intervention (radiotherapy technician).
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Medicine - Isfahan University of Medical Sciences
Street address
Motahari Ave, Omid Hospital
City
Isfahan
Province
Isfehan
Postal code
8184917911
Approval date
2021-07-12, 1400/04/21
Ethics committee reference number
IR.MUI.MED.REC.1400.294

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

Percentage of lung involvement on CT scan after treatment

Timepoint

At the beginning of the study and two months after radiotherapy

Method of measurement

High-resolution lung CT scan without contrast

Secondary outcomes

1

Description

Duration of hospitalization

Timepoint

During the patient's stay in the hospital

Method of measurement

The patient's hospital record

2

Description

Reduction of IL-6

Timepoint

At the beginning of the study and two months after radiotherapy

Method of measurement

Laboratory tests

3

Description

Reduction of CRP

Timepoint

At the beginning of the study and two months after radiotherapy

Method of measurement

Laboratory tests

4

Description

Reduction of D-dimmer

Timepoint

At the beginning of the study and two months after radiotherapy

Method of measurement

Laboratory tests

5

Description

Reduction of LDH

Timepoint

At the beginning of the study and two months after radiotherapy

Method of measurement

Laboratory tests

6

Description

Reduction of Ferritin

Timepoint

At the beginning of the study and two months after radiotherapy

Method of measurement

Laboratory tests

Intervention groups

1

Description

Intervention group: Radiotherapy of both whole lungs in one fraction(a regular single session of radiotherapy) and at a dose of 5 Gy with treatment design by radiation-oncologist and by radiotherapy device equipped with tomotherapy system, in radiotherapy ward of Omid Hospital in Isfahan

Category

Treatment - Devices

2

Description

Control group: For patients in the control group, the treatment design and device set-up and the placement of patients in the treatment position will be done exactly like the intervention group, and instead of X-rays, laser light will be used on the treatment field (chest).

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid hospital

Full name of responsible person

Nadia Najafizade

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Nadia Najafizade
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Radiotherapy
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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