COVID-19: ultra-Low Radiotherapy Dose1: Colorado-1 trial

Published: 17-06-2020
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To determine the pre-liminary efficacy of ultra-low dose radiotherapy for COVID-19 related pneumonia with respiratory insufficiency.

Ethical review	Not approved
Status	Will not start
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON49967

Source
ToetsingOnline

Brief title
COLORADO-1

Condition

- Viral infectious disorders
- Respiratory tract infections

Synonym
COVID-19, pneumonia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: □ COVID-19, □ Pneumonia, □ Radiotherapy

Outcome measures

Primary outcome

The main endpoint will be supplemental oxygen use; 1, 3 and 5 days after

treatment, and at discharge (or after 21 days).

Secondary outcome

Secondary endpoints will be survival, vital parameters, pro-inflammatory

parameters in the blood, and lesion changes on imaging.

Study description

Background summary

Ultra-low dose thoracic radiotherapy was used to treat bacterial and viral pneumonias in the first half of the 20th century, with clinical improvement within 24-48 hours, as reported in over 700 patients. Modern preclinical and clinical data suggest doses of 0.3-1 Gy induce an anti-inflammatory effect. Our hypothesis is that a single fraction of 0.5 Gy (approximately 1% of many cancer treatments) may decrease the host immune response within the lung to decrease lung injury.

Study objective

To determine the pre-liminary efficacy of ultra-low dose radiotherapy for COVID-19 related pneumonia with respiratory insufficiency.

Study design

Single-arm, phase II trial for 25 patients.

Intervention

Ultra-low dose radiotherapy treatment of 0.5 Gy to both lungs.

Study burden and risks

For the patients included in the study, the potential benefit of an alleviating therapy is associated with the treatment performed. Regarding the patients* burden, a transfer to and from the ward to the department of radiation oncology and treatment room. The radiation planning and treatment will take approximately 10 minutes, during which supplemental oxygen will be available (beam on time 1-2 minutes). Due to the ultra-low dose, we expect no side effects from the treatment itself. Furthermore, we will perform a chest X-ray twice, at baseline and at discharge or 21 days after treatment, which will take approximately 5 minutes per X-ray. At baseline, 1, 3 and 5 days after treatment and at discharge or 21 days after treatment, blood will be collected. If possible, this will be combined with blood tests in standard care. All clinical and technical data, including patient characteristics, clinical parameters, blood test results and data form imaging, acquired in standard care, can be used for the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* PCR confirmed positive for SARS-CoV-2
* Progressive respiratory insufficiency with the following:
o National Early Warning Score (NEWS) * 5.
o Respiratory rate * 20/min
o Supplemental oxygen * 6L/min
* DNR (Do not resuscitate, *NRNB*).
* Clinical frailty scale 5-8 at admission.
* Age * 50 years.
* Ability of subject to understand character and individual consequences of the clinical trial.

Exclusion criteria

* Medical indication to be treated at the ICU (intensive care unit).
* Current participation in other intervention studies.
* Prior thoracic radiotherapy only if * grade 3 toxicity has been registered.
* Inability to undergo radiotherapy or transportation, for any reason as determined by the treating physician.
* Alternative diagnosis for respirator insufficiency which is considered to be more likely than COVID-19.
* Current treatment with immunomodulating therapy other than steroids.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	25
Type:	Anticipated

Ethics review

Not approved

Date:	17-06-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL73841.041.20