Reirradiation for recurrent lung cancer in the thorax: overall survival, local control, and toxicity: a phase 2 trial

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The objective of the study is to give a dose of 45 to 60 Gy and therefore to prolong the survival in patients with recurrent lung cancer.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON50584

Source
ToetsingOnline

Brief title
RETHO

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
lung carcinoma, lungcancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Lungcancer, Reirradiation, Thorax

Outcome measures

Primary outcome

The primary objective of the study is to determine the overall survival. In previous studies, the median overall survival was 3 to 8 months, with a median of 6 months. The goal of this study is to treat recurrent lung cancer with high dose radiotherapy to reach a median overall survival of 12 months.

Secondary outcome

The secondary endpoints will be the local control and disease-free survival. Other secondary endpoints are the acute and late toxicity, and the cumulative dose to the organs at risk.

Study description

Background summary

Currently, patients with recurrent lung cancer who will get re-irradiation, are treated with low dose radiotherapy. However, reirradiation with modern techniques and dose summation of previous treatment plan allows us currently to give higher radiation dose, even up to a dose of 45 to 60 Gy, and therefore a radical treatment can be given.

Study objective

The objective of the study is to give a dose of 45 to 60 Gy and therefore to prolong the survival in patients with recurrent lung cancer.

Study design

Observational study, phase 2

Intervention

not applicable

Study burden and risks

In general, patients are fatigued throughout a radiotherapy treatment period. The patient can have a dry or productive cough during or shortly after the radiation course. The patients can have pain with swallowing and a loss of appetite. Symptomatic medication as anti-emetics and pain medication will be provided if required. Five to ten percent of the patients are not able to feed themselves adequately due to severe pain and these patients will be treated with an admission and a placement of a feeding tube. Severe late radiation pneumonitis occuring at 4 - 8 months after the treatment is described and is diagnosed in 10% of the patients and these patients are treated with antibiotics and corticosteroids.

Depending on the technique: 3-D conformal radiotherapy, IMRT, or stereotactic radiotherapy the patient will receive 3 to 35 fractions. With this treatment, the patient will receive a radical treatment instead of a low dose treatment. In comparison with the most commonly used low dose radiation schedule (5 x 4Gy), the patient has to come an extra 30 times to the hospital for irradiation. Because of the study treatment, the follow-up visits are more frequent. In case of low dose radiation, patients will come to the Radiation-Oncologist at 1 and 2 months after treatment and will be referred back to the pulmonologist afterwards. In case of the study-treatment, the patient will visit the hospital more frequently often combined with a CT-scan. In total patients will visit the hospital 8 times extra in combination with a CT scan in 5 follow-up moments. In summary, the patient will be 43 times extra in the hospital. If we use 30 minutes for each kind of extra visit, the burden may reach 21.5 hours assuming complete follow-up of the patient

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

The patients have the tumor close (5 cm or less) to the high dose region (50 Gy EQD2 or more) of the previous irradiation.
Minimal interval between initial treatment with curative intent and reirradiation of 9 months. Treatment in radical setting (at least 45 Gy EQD2) must be possible according to the local investigator.
Treatment options for the patient will be discussed at multidisciplinary oncology board.
Karnofsky score * 70

Exclusion criteria

Patients with more than 3 (oligo)metastases and/or (oligo)metastasis in more than 2 organs and/or (oligo)metastasis which cannot be treated locally.
Inability to retrieve the previous radiation fields, total dose, dose per fraction and time of first radiation series and DVH of the organs at risk.
Not possible to use intervenous CT-contrast.
Pregnant woman.
The use of radiosensitizers such as plaquenil.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-09-2018
Enrollment:	63
Type:	Actual

Ethics review

Approved WMO Date:	25-07-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-07-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-10-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL59876.078.17