# Reirradiation in the thoracic region

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By giving high dose, radical, radiotherapy to patients with recurrent lung cancer, the overall survival can be prolonged and local control rate can be increased which can be done with acceptable toxicity for the irradiated normal tissues.

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON20632

**Bron**
NTR

**Verkorte titel**
RETHO

**Aandoening**

Lung cancer, re-irradiation, thorax

### Ondersteuning

**Primaire sponsor:** Erasmus MC
**Overige ondersteuning:** Dutch Lung Cancer Research Group

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

Overall survival

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

Within this study we want to investigate if a dose of 45 to 60 can prolong the overall survival in patients with recurrent lung cancer.

Patients of 18 years or older with recurrent lung cancer in the thorax who have been irradiated previously to the same region are included. The

patients have the tumor close (5 cm or less) to the high dose region (50 Gy EQD2 or more). The minimal interval between initial treatment with curative intent and reirradiation has to be 9 months. Treatment in radical setting (at least 45 Gy EQD2) must be possible. Patients having more than 3 (oligo)metastases and/or (oligo)metastases in more than 2 organs and/or (oligo)metastases which can not be treated locally, are not a candidate.

The primary endpoint of the study is survival, our goal is to reach a median overall survival of 12 months. The secondary endpoint are local control, disease-free survival, acute and late toxicity and cumulative dose to the organs at risk.

### Doel van het onderzoek

By giving high dose, radical, radiotherapy to patients with recurrent lung cancer, the overall survival can be prolonged and local control rate can be increased which can be done with acceptable toxicity for the irradiated normal tissues.

### Onderzoeksopzet

Pre-treatment evaluation (screening)

Pre-study entry (baseline)

Radiotherapy treatment (period is different for each patients; maximum of 35 fractions)

FU visit 1: 1 week after re-RT

FU visit 2 (by phone): 3 weeks after re-RT

FU visit 3: 12 weeks after re-RT

FU visit 4: 6 months after re-RT

FU visit 5: 9 months after re-RT

FU visit 6: 12 months after re-RT

FU visit 7: 18 months after re-RT

FU visit 8: 24 months after re-RT

FU visit 9: 30 months after re-RT

FU visit 10: 36 months after re-RT

**Onderzoeksproduct en/of interventie**

Radiotherapy

# Contactpersonen

## Publiek

M. Duijm
Rotterdam
The Netherlands
06-50033538

## Wetenschappelijk

M. Duijm
Rotterdam
The Netherlands
06-50033538

# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Cytological or histological proof of the current tumor: NSCLC or large cell lung cancer with neuro-endocrine differentiation;

• Current tumor located close (5 cm or less) to the high dose region (50 Gy EQD2 or more) of the previous radiation;

• Interval between initial treatment with curative intent and reirradiation is ≥9 months;

• Age ≥ 18 years;

• If woman of childbearing potential: use of adequate contraceptive precautions;

• Written informed consent;

• FEV1 > 40% of predicted;

• Karnofsky score ≥ 70;

• Treatment in radical setting (at least 45 Gy EQD2) is possible according to the local investigator;

• Staging of recurrent lung cancer is performed with a whole body CT scan and PET scan;

• Treatment options for the patient will be discussed at multidisciplinary oncology board.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Pregnancy;

• 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;

• Contraindication to use intravenous CT contrast;

• The use of radiosensitizers such as plaquenil;

• 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.

## Onderzoeksopzet

### Opzet

Type: Interventie onderzoek

| | |
|---|---|
| Onderzoeksmodel: | Anders |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-08-2018 |
| Aantal proefpersonen: | 63 |
| Type: | Verwachte startdatum |

## Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 04-06-2018 |
| Soort: | Eerste indiening |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

| Register | ID |
|---|---|
| NTR-new | NL7052 |
| NTR-old | NTR7257 |
| Ander register | : METC: MEC-2017-534 / ABR: NL59876.078 |

# Resultaten