# Randomized trial on chest irradiation in extensive disease small cell lung cancer.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON21608

**Source**
NTR

**Brief title**
CREST

**Health condition**

SCLC;ED-SCLC; PCI; thoracic radiotherapy; brain metastasis; prophylactic cranical irradiation; extensive disease small cell lung cancer; klein-cellig longkanker; radiotherapie

### Sponsors and support

**Primary sponsor:** VU University medical center
Dept. of Radiation Oncology
**Source(s) of monetary or material Support:** VU University medical center
Dept. of Radiation Oncology

### Intervention

### Outcome measures

**Primary outcome**

The primary endpoint of this trial is to achieve an increase in 1 year survival of 10% (from 27 % to 37%; HR=0.76).

The Kaplan-
Meier method will be used to estimate survival at different time points, and the logrank two sided test will be used to compare therapeutic arms according to the intent to treat policy.

### Secondary outcome

The secondary endpoints are local control, pattern of failure and toxicity. Local control is defi ned as the absence of disease progression in the treated lobe/lung.

## Study description

### Background summary

Intrathoracic tumor control is a major problem in ED-
SCLC. Over 75% of patients have persisting intra-
thoracic disease after initial chemotherapy, and about 90% manifest intra-
thoracic disease progression at 1 year after completing initial chemotherapy [Slotman,2007].

In a trial reported by Jeremic et al., patients with ED-
SCLC who had a complete response at sites of distant disease, were randomized to thoracic r adiotherapy (54 Gy in 18 days) in combination with low dose chemotherapy or an additional f our cycles of cisplatin/etoposide chemotherapy only [Jeremic 1999]. A total of 109 patients w ere randomized after induction chemotherapy, and the reported median (17 versus 11 month s) and 5-
year survivals (9.1% v 3.7 %,) was far higher than has been reported by any other group for E D-SCLC. This study has not yet been repeated.

In the absence of promising systemic agents that can improve local response, a logical step would be to evaluate the role of thoracic irradiation in patients with ED-
SCLC who respond to chemotherapy.

### Study objective

The objective of this study is to investigate whether thoracic radiotherapy can improve 1year survival in patients with extensive disease SCLC, following a response to chemotherapy, from 27% to 37%, as measured from time of randomisation after chemotherapy

**Study design**

PCI and thoracic radiotherapy will commence within six weeks after the completion of chemot herapy.
However, PCI and thoracic radiotherapy can only start at least 2 weeks after the last administ ration of chemotherapy, when the acute Grade 2 or higher toxicity of chemotherapy has resol ved.

Acute toxicity will be recorded during treatment, and reported on the acute toxicity checklist and at end of treatment, according to CTCAE v 3.0.

Patients will be followed up at 6 weeks and at 3, 6, 9 and 12 months after randomisation in b oth arms, and, subsequently every 6 months until death.
This follow-up schedule must adhere to all patients, in both treatment arms.

The following examinations will be performed at each follow-up:

- Medical history and physical evaluation

- Chest X-ray

**Intervention**

Patients with a response to chemotherapy, will receive prophylactic cranial irradiation 20 Gy in 5 fractions or 30 Gy in 10 fractions 4-5 times per week. And they
will be randomized to receive either thoracic irradiation or no further therpy. For thoracic radiotherapy, 30 Gy will be delivered in 10 fractions, 4-5 times per week.

# Contacts

**Public**
VU University medical center <br>
Department of Radiation Oncology <br>P.O.Box 7057

B.J. Slotman
Amsterdam 1007 MB
The Netherlands
+31 (0)20 4440414
**Scientific**
VU University medical center <br>
Department of Radiation Oncology <br>P.O.Box 7057

B.J. Slotman
Amsterdam 1007 MB

The Netherlands
+31 (0)20 4440414

# Eligibility criteria

## Inclusion criteria

- Cytologically or histologically proven small cell lung cancer
-Documented extensive disease (see appendix D) before the start of chemotherapy

-Any response after 4 to 6 cycles of initial chemotherapy (chemotherapy regimen and response evaluation according to the standard institution policy, provided that none of the existing lesions progressed)

-Chemotherapy (preferably platinum-etoposide; other regimens need approval of study-coordinator) completed. A patient can be randomized prior to the end of chemotherapy if the date of last chemotherapy is known and not more than 2 weeks in the future, and if the response criteria are met on the date of randomization. Study treatment should start within 6 weeks after last date of chemotherapy.

- Maximum interval of 6 weeks between last chemotherapy administration and randomization

-No evidence of brain metastases or leptomeningeal metastases (A contrast enhanced CT MRI scan of the brain is mandatory in case of clinical suspicion of brain metastases)

-No evidence of pleural metastases or pleuritis carcinomatosa

-No prior radiotherapy to the brain

-No prior radiotherapy to the thorax

- Age 18 years or older

-Performance status 0 to 2 (WHO scale, see Appendix B)

-Patient must be willing to receive chest irradiation

-Before patient registration/randomization, written informed consent must be given according to ICH/GCP, and national/local regulations

-Volume should be encompassable in acceptable radiation fields
14. Volume should be encompassable in acceptable radiation fields.

### Exclusion criteria

None

## Study design

### Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-01-2009 |
| Enrollment: | 483 |
| Type: | Actual |

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion

| | |
|---|---|
| Date: | 07-11-2008 |
| Application type: | First submission |

# 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 |
|---|---|
| NTR-new | NL682 |
| NTR-old | NTR1527 |
| Other | VU METC : 2008-266 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd |

# Study results

**Summary results**
Use of thoracic radiotherapy for extensive stage small-cell
lung cancer: a phase 3 randomised controlled trial , Slotman et al. The Lancet September 14, 2014 <br>
http://dx.doi.org/10.1016/
S0140-6736(14)61085-0 <br>
Comments in http://dx.doi.org/10.1016/
S0140-6736(14)61252-6