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

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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 ...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21608

Bron
Nationaal Trial Register

Verkorte titel
CREST

Aandoening

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

Ondersteuning

Primaire sponsor: VU University medical center
Dept. of Radiation Oncology
Overige ondersteuning: VU University medical center
Dept. of Radiation Oncology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

None

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2009
Aantal proefpersonen:	483
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	07-11-2008
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	NL682
NTR-old	NTR1527
Ander register	VU METC : 2008-266
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
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
http://dx.doi.org/10.1016/
S0140-6736(14)61085-0
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S0140-6736(14)61252-6