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

Published: 11-12-2008
Last updated: 16-11-2024

to evaluate the role of thoracic irradiation in patients with ED-SCLC who respond to chemotherapy and to assess the effect on 1 year survival

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

Summary

ID

NL-OMON38229

Source
ToetsingOnline

Brief title
CREST

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
lung cancer, small cell lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Er is een subsidie voor datamanagement ondersteuning van het Koningin Wilhelmina fonds

Intervention

Keyword: irradiation, radiotherapy, small cell lung cancer

Outcome measures

Primary outcome

1 year survival

Secondary outcome

toxicity

pattern of recurrent disease

Study description

Background summary

Chemotherapy is the cornerstone in the treatment of extensive disease small cell lung cancer (ED-SCLC), and four to six cycles of chemotherapy without maintenance therapy is current standard. However, survival in patients presenting with ED-SCLC is poor and has shown little improvement in the past few decades.
The notable exception was the survival benefit reported in a phase III EORTC trial evaluating prophylactic cranial irradiation (PCI) versus no PCI following any response to induction chemotherapy Symptomatic brain metastases were significantly more frequent in controls (40% versus 15%), more of whom also died of SCLC (80% versus 68%). More patients in the PCI arm also received salvage chemotherapy at the time of disease recurrence. PCI is the new standard of care in all patients with SCLC who respond to chemotherapy.
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 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 radiotherapy. The reported median and 5-year survivals, was far higher than has been reported by any other group for ED-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 and to assess the effect on 1 year

survival.

Study objective

to evaluate the role of thoracic irradiation in patients with ED-SCLC who respond to chemotherapy and to assess the effect on 1 year survival

Study design

This is a multicenter phase III randomized trial. Patients with cytologically or histologically proven ED small cell lung cancer
will be treated with chemotherapy.
Patients with a response will receive prophylactic cranial irradiation and will be randomized to receive either thoracic
irradiation or no further therapy

Intervention

thoracic irradiation

Study burden and risks

No extra hospital visists or interventions. Risk for extra toxicity due to thoracic irradiation

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

18 years or older
Cytologically or histologically proven small cell lung cancer
Documented extensive disease before the start of chemotherapy
Any response after 4 to 6 cycles of initial chemotherapy

Exclusion criteria

prior radiotherapy to the brain or the thorax
evidence of brain metastases or leptomeningeal metastases, pleural metastases or pleuritis carcinomatosa

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	18-02-2009
Enrollment:	412
Type:	Actual

Ethics review

Approved WMO Date:	11-12-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-02-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL24556.029.08