Concurrent ONce-daily VErsus twice-daily RadioTherapy: A 2-arm randomised controlled trial of concurrent chemo-radiotherapy comparing twice-daily and once-daily radiotherapy schedules in patients with limited stage small cell lung cancer (SCLC) and good performance status.

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To compare the primary endpoint (overall survival) between the two arms of the studySecondary endpoints are:Local progression-free survivalMetastases-free survivalCTCAE v3.0 toxicityChemotherapy dose intensityRadiotherapy dose intensity

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

Summary

ID

NL-OMON33659

Source
ToetsingOnline

Brief title
CONVERT

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified
- Respiratory tract neoplasms

Synonym
lung cancer, oat cell carcinoma, small cell lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: EORTC
Source(s) of monetary or material Support: EORTC en Christie- Hospital NHS Trust;MRC

Intervention

Keyword: Concurrent chemoradiation, once daily radiotherapy, Small cell lung cancer Limited disease, Twice dailly radiotherapy

Outcome measures

Primary outcome

Primary endpoint: overall survival

Secondary outcome

Secondary endpoints;

Local progression-free survival

Metastases-free survival

CTCAE v3.0 toxicity

Chemotherapy dose intensity

Radiotherapy dose intensity

Study description

Background summary

The standard treatemtn of patiënts with SCLC LD consists of 4 cycles of chemotherapy
(generally platinum-derivates with etoposide). Concurrently with a part of the chemotherapy radiotherapy is given to the lungtumor, mostly during the second and the third cycle. The standard dose of radiotherapy is 45-50 Gray (Gy), adminstered in 25-30 fractions. The optimal dose of radiotherapy, the optimal frationation and the optimal timing of combination with chemotherapy is not known. The best results reported in a phase III study are obtained with 4 cycles ofchemotherapye and radiotherapye 45 Gy/2 x per day 1.5 Gy, started on day 1 van de chemotherapy. The 5-years survival was 26% in this study. Improvement of these results can possibly be obtained by a higher dose of radiotherapy. Based upon several phase II studies is chosen for av comparison of 45 Gy/2xdd 1.5Gy/30 fractions with 66 Gy/1xdd 2Gy/33 fractions. The chemotherapy is identical in both arms of the study

Study objective

To compare the primary endpoint (overall survival) between the two arms of the study
Secondary endpoints are:
Local progression-free survival
Metastases-free survival
CTCAE v3.0 toxicity
Chemotherapy dose intensity
Radiotherapy dose intensity

Study design

Multicentre randomised phase III trial. Patients are randomised to one of the two treatment arm with 1;1 randomisation: patients will be randomly allocated to treatment, using a minimization procedure

Intervention

Control arm:
Four to six cycles of Cisplatin 25mg/m2 iv D1 Etoposide 100 mg/m2 D1-3 with concurrent BD radiotherapy 45 Gy in 30 twice-daily fractions over 3 weeks, 5 days per week from day 22 of cycle 1

Experimental arm:
Four to six cycles of Cisplatin 25mg/m2 iv D1 Etoposide 100 mg/m2 D1-3 with concurrent oD radiotherapy 66 Gy in 33 daily fractions over 6.5 weeks, 5 days per week from day 22 of cycle 1

Study burden and risks

In the intervention-arm patients receive three more fractiions of radiotherapy (33 i.po. 30). In the intervention-arm patients will be irradiated during 6.5 weeks, in the standard-arm during three weeks.

The higher dose of radiotherapy can cause more acute and late toxicity.

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

a)either sex, age *18 years
b) Performance status ECOG grade 0-1 (appendix 1).
c) Histologically or cytologically confirmed SCLC
d) No patients with mixed small-cell and non-small-cell histologic features
e) No history of previous malignancy in the last 5 years (except non melanomatous skin or in-

situ
cervix carcinoma). Patients with previous malignancies (except breast cancer) and in remission for at least 5 years can be included.
f) Limited stage disease (Veterans Administration Lung Cancer Study Group) ie patients whose disease can be encompassed within a radical radiation portal.
g) No pleural or pericardial effusions proven to be malignant
h) RT target volume acceptable by the local radiotherapist
i) Pulmonary function
a. FEV1 >1 litre or 40% predicted value
b. KCO (DLCO/VA) >40%predicted
j) Maximum of one of the following adverse biochemical factors:
a. Serum alkaline phosphatase more than >1.5 times the upper limit of normal (ULN)
b. Serum sodium < Lower limit of Normal
c. Serum LDH > UNL
k) Normal serum creatinine and calculated creatinine clearance * 50 ml/min. If calculated creatinine
clearance is <50 ml/mn according to the Cockroft and Gault formula (appendix 5), an EDTA clearance should be performed
l) Adequate haematological function
a. Neutrophils >1.5 x 109/l
b. Platelets >100 x 109/l
r) Patient has read the patient information sheet and has signed the consent form.
s) Patients available for follow-up
o) Considered fit to receive any of the trial regimens

Exclusion criteria

Other previous or concomitant illness or treatment which in the opinion of the clinician will interfere with the trial treatments or comparisons
Prior surgical resection of the primary tumour, no prior radiotherapy for lung cancer
Considered fit to receive any of the trial regimens
Female patients must satisfy the investigator that they are not pregnant, or are not of childbearing
potential, or are using adequate contraception. Men must also use adequate contraception, as etoposide is clastogenic.
Patients who are breastfeeding
Patients who are not available for adequate follow-up

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2009
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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
ISRCTN	ISRCTN91927162
CCMO	NL24565.018.08