Phase III study comparing post-operative conformal radiotherapy to no post-operative radiotherapy in patients with completely resected non-small cell lung cancer and mediastinal N2 involvement.

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Main:the objective of this randomized trial would be to study disease free survival (DFS) in a population with completely resected NSCLC with homolateral lymph node mediastinal involvement histological or cytological proven. Who will randomly be...

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

Summary

ID

NL-OMON33550

Source
ToetsingOnline

Brief title
LungART (Lung Adjuvant Radiotherapy Trial)

Condition

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

Synonym
non small cell lung cancer; lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: MAASTRO clinic
Source(s) of monetary or material Support: CKTO (KWF)(uitvoering datamanagement)

Intervention

Keyword: mediastinal N2 involvement, non-cell lung cancer, Post operative radiotherapy

Outcome measures

Primary outcome

disease free survival (DFS)

Secondary outcome

- assessment of treatment of acute and late toxicity (with identification of

predictiev factors of toxicity)

- local control

- patterns of recurrence

- overall survival

- second cancers

- prognostic and predictive factors on DFS and OS

Study description

Background summary

Over one million people are diagnosed with lung cancer every year throughout the world. About 80% of them have non-small cell lung cancer (NSCLC) whtich includes adenocarcinoma, squamous cell and large cell carcinoma. Considering all stages together, the 5-year survival rate in NSCLC patients does not exceed 14%. Most long term survivors are patients having had a complete surgical resection of their tumor. The latter, considerd as the best treatment option, is only achievable in about 30% of the patients. Even in this highly selected group of patients, there is still a high risk of both local and distant failure. Adjuvant treatments such as chemotherapy (CT) and radiotherapy(RT)

have therefore been evaluated in order to improve their prognosis. In view of the high proportion of the patients still suffering form local tumour recurrence after a complete resection and adjuvant chemotherapy, a new interest in post-operative radiotherapy (PORT) occurred. However, PORT has been for years a very controversial issue and still is.
A new radomized study should take into consideration all we know about toxicity. Conformational radiotherapy should be proposed to all operated patients as their mediastinal location and anatomy may vary after surgery, especially pneumectomy, in order to decrease the morbidity.

Study objective

Main:
the objective of this randomized trial would be to study disease free survival (DFS) in a population with completely resected NSCLC with homolateral lymph node mediastinal involvement histological or cytological proven. Who will randomly be assigned to receive conformational PORT of not to receive PORT. Local control will be studied carefully. Overall survial will be evaluated with a minimal follow-up of 5 years in the two groups.

Secondary:
- impact of thoracic radiotherapy on toxicity and in particular cardiac and pulmonary toxicity (with identification of plasmatic predictif factors of toxicity)
- local control
- patterns of recurrence
- overall survival (OS)
- second cancers
- prognostic factors and predictiev faactors of treatment effect on DFS and OS.

Study design

Phase III multicentre international trial with possible individual direct benefit to the patient comparing after randomization mediastinal PORT (54 Gy/30 fractions/ 6 weeks) to no PORT.

Intervention

Conformal postoperatiev thoracacic radiotherapty (PORT) in experimental arm. PORT consists of 54 Gy in 30 fractions of 1,8 Gy. The radiotherapy will be given one time a day, 5 days per week.

Study burden and risks

Possible benefits and risks
The benefit due to participation is that the patient will maybe avoid a

treatment which may not be proven effective after all. The randomization takes care of at random allocation of the experimental treatment (radiotherapy after surgery) or the standard treatment.
Another benefit of this trial is to gain more insight into the treatment of lung cancer patients.

Possible side effects of radiotherapy are:
fatigue, pain during swallow, irratiation of the skin and severe coughing. In the time period after the end of radiotherapy radiotion pneumonitis can be occur. Patients may develop a less lower lung function after the treatment with radiotherapy and can develop shortness of breath. The patient will be under monitoring to prevent these side effects.

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

1) Histological evidence of non-small cell lung cancer (NSCLC)
2) Complete resection with mediastinal lymph node exploration
3) Pathologically or cytologically documented mediastinal nodal involvement, at the time of surgery if no preoperative chemotherapy or before preoperative chemotherapy, according to the criteria of the joint AJCC and UICC classification,
4) No past history of chest radiotherapy
5) Prior chemotherapy is allowed
6) Patient aged >18 years
7) WHO 0 or 1
8) Adequate pulmonary function
9) No severe cardiac or pulmonary disease,
10) Possibility of long-term follow-up
11) Information given to patient and signed informed consent form.

Exclusion criteria

1) Documented metastases,
2) Pleural or pericardial effusion,
3) Synchronous contra-lateral lung cancer,
4) Clinical progression during post-operative chemotherapy,
5) Incomplete resection
6) Lack of mediastinal lymph node exploration,
7) Previous chest radiotherapy
8) Intention of concomitant chemotherapy during radiotherapy
9) Weight loss before surgery more than 10%
10) Evidence of severe or uncontrolled systemic disease as judged by the investigator
11) Recent (< 6 months) severe cardiac disease
12) Past or current history of neoplasm other than non-small cell lung cancer
13) Pregnancy or breast feeding or absence of adequate contraceptive measures during treatment
14) Patients who cannot be adequately followed up
15) Patient deprived of freedom or under guardianship.

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:	Recruitment stopped
Start date (anticipated):	01-09-2008
Enrollment:	195
Type:	Anticipated

Ethics review

Approved WMO Date:	14-11-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	23-01-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	16-04-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT00410683
CCMO	NL23602.068.08