ACOSOG Z4099/ RTOG 1021 A randomized phase III study of sublobular resection (+/- brachytherapy) versus stereotactic body radiation therapy in high risk patients with stage I non-small cel lung cancer (NSCLC)

Published: 18-07-2012
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This study is important in that not only will we learn information about the true oncologic differences between these therapies, we will also determine the relative impact of these therapies on pulmonary function and quality of life.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON36861

Source
ToetsingOnline

Brief title
ACOSOG Z4099

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
lung cancer, Lung carcinoma

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Lung cancer, NSCLC, stage I, Stereotactic body radiation (SBRT), Sublobar resection (SR)

Outcome measures

Primary outcome

To ascertain whether patients treated by SBRT have a 3-year overall survival

(OS) rate that is no more than 10% less than patients treated with SR.

Secondary outcome

To compare the following items between SR and SBRT:

* Loco-regional recurrence-free survival.

* Disease-free survival.

* Grade 3 or higher specific adverse event profiles

* Pulmonary function.

* Adverse events and PFTs in each arm for patients with low or high Charlson

comorbidity index scores, including a test interaction between Charlson

comorbidity index scores (low vs. high) and treatment arm.

Correlative science objectives:

* To compare the quality-adjusted survival between the treatments SBRT and SR

in terms of time to death (primary) and time until recurrence (secondary).

* To examine whether pre-operative and post-operative clinically significant

deficits in previously-identified prognostic PRO domains (overall QOL, fatigue, anxiety, dyspnea) are associated with shorter patient survival in this patient population and to compare the relative effectiveness of each treatment (SBRT and SR).

* To contribute to an ACOSOG bank of normative data in order to improve short/long term outcomes of cancer patients by identifying patients experiencing clinically significant deficits in patient-reported outcomes and the relationship to genetic variables.

* To explore whether blood based biomarkers, including osteopontins, will be able to predict which patients will be at high risk for recurrence by treatment with either SBRT or SR.

* To explore whether blood based biomarkers, including TGF-*1, will be able to predict which patients will be at high risk for pulmonary complications by treatment with either SBRT or SR.

Study description

Background summary

Stage I lungcancer is potentially curable. Patients can be divided into 3 categories based on their pre-existing medical history: 1) standard risk operable 2) High-risk operable patients and 3) medically inoperable. Patients in category 1 and 3 are treated with respectively lobectomy/pneumonectomy or stereotactic body radiation therapy (SBRT). For patients in category 2 better therapies are needed.
There have not been any prospective, randomized trials to compare the efficacy or the toxicity profile of SR to SBRT in high risk patients. Currently, it is difficult to make comparisons between the therapies because in the available literature the definitions of local recurrence, local control, and regional recurrence are not uniform and toxicity is scored by different means. This has led to different perceptions and interpretations of the published literature

relating to these modalities.

Study objective

This study is important in that not only will we learn information about the true oncologic differences between these therapies, we will also determine the relative impact of these therapies on pulmonary function and quality of life.

Study design

This is a prospective, randomized Phase III trial comparing SR and SBRT for high-risk patients with operable lung cancer.

Intervention

Patients in both groups will get an intervention. Half of patients will be treated with a sublobar resection. The other half will be treated with stereotactic body radiation therapy.

Study burden and risks

Patients in both arms (SR and SBRT) can experience adverse events correlated to the treatment. Because both treatments are also used for patients outside this study, we expect no additional chance on toxicity for the participating patients.
All participating patients may have to visit the hospital more often than non-participating patients. On eight visits they will be asked to complete a questionnaire. This wil cost an extra 5 to 15 minutes. The visits itself and the imaging during follow-up will not differ from the follow-up in non-participating patients.

Contacts

Public
Vrije Universiteit Medisch Centrum

de Boelelaan 1117
Amsterdam 1081HV
NL
Scientific
Vrije Universiteit Medisch Centrum

de Boelelaan 1117
Amsterdam 1081HV

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age: 18 years or older
ECOG performance status of 0, 1 or 2
Patients at high risk for surgery (see protocol for criteria)
Lung nodule suspicious for NSCLC (biopsy confirmation is strongly recommended)
Clinical stage Ia or Ib, no evidence of metastases
All clinically suspicious mediastinal lymph nodes confirmed negative
Tumor verified by thoracic surgeon to be in location that permits sublobar resection

Exclusion criteria

Evidence of metastases
Tumor >2 cm of bronchial tree
Prior intrathoracal radiotherapy
Previous chemotherapy or surgery for lungcancer treated on this protocol
Pregnant or lactating
Invasive cancer < 3 years prior to registration (exception, non melanoma skin cancer or in-situ cancer)

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO Date:	18-07-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-11-2012
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
ClinicalTrials.gov	NCT01336894
CCMO	NL40733.029.12