Dose-escalation by boosting radiation dose within the primary tumor on the basis of a pre-treatment FDG-PET-CT scan in stage IB, II and III NSCLC: A randomized phase II trial

Published: 09-11-2009
Last updated: 06-05-2024

The primary objective of this study is to determine the freedom from local failure in patients alive at 1 year

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

Summary

ID

NL-OMON43597

Source
ToetsingOnline

Brief title
PET Boost

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
lung cancer, non-small cell lung carcinom

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: KWF;EU

Intervention

Keyword: 18F-HX4 scan, FDG-PET scan, non- small cell lung cancer, radiotherapy

Outcome measures

Primary outcome

Freedom from local failure in patients alive at 1 year

Secondary outcome

Toxicity

Overall survival

Quality of life

Distant metastases

Local and regional failures outside PTV

Correlation between intra-tumor recurrence 3 and 12 months post radiotherapy

based on average PET CT , 18F HX4 and DCE-CT scan

Correlation between intra-tumor recurrence 3 and 12 months post radiotherapy

based on average PET CT and 18F HX4.

Correlation between distant metastases and 18F HX4 uptake in the primary tumor.

Study description

Background summary

Local tumor failure remains high in patients with stage IB, II and III
non-small cell lung cancer (NSCLC), with local progression free survival (LPFS)
rates of about 30 %, even with concurrent chemo-radiation

Radiation dose-escalation can further increase local tumor control rates, especially when radiotherapy is delivered in a short overall treatment time. Because of dose-limiting toxicity, individualized radiation dose-prescription on the basis of normal tissue dose constraints has been investigated, in conjunction with target volume definition on the basis of 18F-deoxyglucose (FDG)-Positron Emission Tomography (PET)-CT scans. The pre-treatment FDG uptake in the tumor, quantified by the SUV-value and the pre-radiation volume of the tumor is prognostic for the local tumor control.
The question however remains whether delivering a higher radiation dose to the most avid FDG-uptake areas within the tumor may improve local tumor control.
A randomized phase II study will be conducted in patients with inoperable stage IB, II or III non-small cell lung cancer (NSCLC). The patients will be randomized to receive the standard 66 Gy given in 24 fractions with an integrated boost to the primary tumor as a whole (Arm A) or with an integrated boost to the 50% SUVmax of the primary tumor (of the pre-treatment PET FDG scan) (Arm B)

Study objective

The primary objective of this study is to determine the freedom from local failure in patients alive at 1 year

Study design

This study is a randomized multi-institutional phase II trial

Intervention

Radiotherapy with integrated boost on primary tumor on the basis of a pre-treatment FDG-PET-CT scan

Study burden and risks

The treatment in this study will give rise to side effects comparable to standard radiotherapy of non-small cell lung cancer (dysphagia, radiation pneumonia). The side effects are possibly more severe but probably reversibel.

Contacts

Public
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
AMSTERDAM 1066CX

NL
Scientific
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
AMSTERDAM 1066CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Patients > 18 years with any subtype of pathologically proven, non-small cell lung cancer. The diagnosis may be established from biopsy or cytology obtained from the primary tumor and/ or from metastatic lymph nodes.
2. Minimal diameter of the primary tumor 4 cm, to allow boosting of sub-volumes.
3. UICC Stage T2-4, N0-3, M0 disease (TNM definition see appendix 2).
4. Only stage IB-II patients who are not candidates for surgery are eligible
5 Measurable disease at registration.
6. ECOG-performance status < 2 (see appendix 6)
7. Lung function: FEV1 and DLCO at least 40 % of the age-adjusted normal value
8. Willing and able to give a written informed consent.
9. Patients with locoregional recurrent lung tumor following surgery or a second primary cancer (at least 3 years after treatment) are eligible, unless a pneumonectomy was performed.
10. SUVmax in the pre-treatment FDG-PET scan><= 5 for the primary tumor.
11. Adequate organ function, including the following:
a. Adequate bone marrow reserve: absolute neutrophil (segmented and bands) count (ANC) *1.5 x 109/L, platelets * 100 x 109/L, and hemoglobin * 9 g/dL.
b. Hepatic: bilirubin * 1.5 times the upper limit of normal (* ULN); alkaline phosphatase (AP), aspartate aminotransferase (ASAT), and alanine aminotransferase (ALAT) * 3.0 * ULN.
c. Renal: calculated creatinine clearance (CrCl) ><= 45 ml/min based on the original weight

based Cockcroft and Gault formula
12 For women: Must be surgically sterile, postmenopausal, or compliant with a highly reliable contraceptive method (failure rate <1%) during and for 6 months after the treatment period, must not be breast-feeding.
13. For men: Must during chemotherapy take adequate contraceptive measures.

Exclusion criteria

1. Prior radiotherapy to the thorax.
2. Clinical superior vena cava syndrome, malignant pleural effusion or malignant pericardial effusion.
3. Tumor growth in large blood vessels on spiral CT scan or encasement >50 %
4. Multiple nodules in the same or ipsilateral lobe(s).
5. Post-obstructive atelectasis or infiltration that cannot be distinguished from tumor on a CT-PET scan.
6. Patients with a diagnosis of other cancer within the last 3-years (except in situ carcinoma*s and / or non-melanoma skin cancer).
7. Pregnant or lactating women.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-10-2010
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO Date:	09-11-2009
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	31-10-2012
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	22-01-2014
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	28-03-2014
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	15-07-2014
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	11-05-2015
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	25-02-2016
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO	

Date:	29-09-2016
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NCT01024829
CCMO	NL28000.031.09