A randomized phase III study of adjuvant chemotherapy in patients with completely resected Non-Small-Cell Lung Cancer and low risk for recurrence: NVALT-8A

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The primary aim of the study is to investigate whether it is possible to select patients by PET in a good prognosis group (i.e. low SUV) who will not benefit from adjuvant chemotherapy.

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

Summary

ID

NL-OMON34015

Source
ToetsingOnline

Brief title
NVALT-8A

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
lungcancer, Non-smal cell lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: KWF CKTO

Intervention

Keyword: adjuvant chemotherapy versus observation, low-risk, NSCLC

Outcome measures

Primary outcome

Recurrence-free survival.

Secondary outcome

Secondary end-points are overall survival, dose intensity of subsequent cycles,

quality of life, toxicity, health economics. Exploratory endpoints are analysis

of blood and tumor samples for prognostic markers, genomics/proteomics.

Study description

Background summary

The use of adjuvant chemotherapy and especially cisplatin in combination therapy in patients with completely resected early-stage NSCLC improves disease-free and overall survival. Subgroup analyses suggested that not all patients benefit from chemotherapy, but how to select patients for treatment is still not clear. In this study we select patients by FDG-PET in a good prognosis group using FDG avidity as measured by the standardized uptake value (SUV). The hypothesis of this study is that in patients with resected NSCLC and low SUV will not benefit from adjuvant chemotherapy.

Study objective

The primary aim of the study is to investigate whether it is possible to select patients by PET in a good prognosis group (i.e. low SUV) who will not benefit from adjuvant chemotherapy.

Study design

This is a randomized multicenter phase III study. Patient with a low SUV of the primary tumor prior to surgery will be randomised to four cycles of cisplatin-based chemotherapy or observation in a non-inferiority design. A total of 864 patients will be entered in the study (432 patients in each arm) in 4 years. The follow up will continue for 5 years further, at the end of which a total of 150 events would be observed allowing the comparison (alpha=0.05 one-sided log-rank test.) of the curves by treatment arm with 80% power to test the non-inferiority of no chemotherapy to adjuvant chemotherapy.

Intervention

Patients will be randomized to observation or will be treated with 4 cycles of one of the four cisplatin-based chemotherapy regimens:
-Docetaxel (75 mg/m2 day 1) and cisplatin (75 mg/m2 day 1) Q 3 weeks
-Gemcitabine (1250 mg/m2 day 1 and 8) and cisplatin (75 mg/m2 day 1) Q 3 weeks
-Pemetrexed (500 mg/m2 day 1) and cisplatin (75 mg/m2 day 1) Q 3 weeks
-Vinorelbine (25 mg/m2 day 1 and day 8) and cisplatin (75 mg/m2) day 1 Q 3 weeks

Study burden and risks

Standard treatment of these patients consists of cisplatin based adjuvant chemotherapy. The hypothesis that patients in the good prognostic group will have no survival benefit of adjuvant chemotherapy. The experimental arm is no chemotherapy. Follow-up of the patients will be performed according to the national guidelines.

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

- Age >= 18 years
- Patients with resectable NSCLC
- SUVmax < 10
- Performance score <= 2 before chemotherapy.
- Adequate organ function before administration of chemotherapy, including:
Adequate bone marrow reserve: ANC >= 1.5 x 109/L, platelets >= 100 x 109/L.
Hepatic: bilirubin <= 1.5 x ULN, AP, ALT, AST <= 3.0 x ULN.
Renal: calculated creatinine clearance >= 60 ml/min based on the Cockroft and Gault formula.
- Patients must sign and date a written Independent Ethics Committee approved informed consent form.

Exclusion criteria

- Patients with wedge or segmental resection.
- Patients with stage IA NSCLC
- Prior chemotherapy or radical radiotherapy for NSCLC.
- Any unstable systemic disease (including active infection, uncontrolled hypertension, unstable angina, congestive heart failure, myocardial infarction within the previous year, severe cardiac arrhythmia requiring medication, hepatic, renal or metabolic disease).
- Concomitant treatment with any other experimental drug under investigation.
- History of any active malignancy (other than NSCLC) unless treated more than 3 years with curative intent and no recurrence, except non-melanoma skin cancer or in situ cervical cancer.
- Pregnancy
- Women of child-bearing potential not using effective means of contraception

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):	01-06-2007
Enrollment:	864
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Alimta
Generic name:	Pemetrexed
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Cisplatin
Generic name:	Cisplatin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Gemzar
Generic name:	Gemcitabine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Navelbine
Generic name:	Vinorelbine

Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Taxotere
Generic name:	Docetaxel
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	13-07-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	13-07-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
EudraCT	EUCTR2007-002644-21-NL
CCMO	NL17134.042.07