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

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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.

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27925

Bron
Nationaal Trial Register

Verkorte titel
NVALT 8A

Aandoening

non-small-cell lung cancer

Ondersteuning

Primaire sponsor: NVALT oncology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main endpoint is recurrence-free survival.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

4 years follow-up

Onderzoeksproduct en/of interventie

Patients will be randomised to observational 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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age >= 18 years

2. Patients with NSCLC, pT2N0, pT1N1, pT2N1, pT3N0 and pT3N1

3. SUVmax < 10

4. Patients with NSCLC who had a surgical R0 resection

5. Performance score <= 2 before CT

6. 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.

7. Patients must sign and date an approved Informed Consent form.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients with incomplete or inadequate pulmonary resections. incomplete preoperative or intraoperative staging, wedge or segmental resection.

2. Prior chemotherapy or radical radiotherapy.

3. 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).

4. Concomitant treatment with any other experimental drug under investigation.

5. 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.

6. Pregnancy

7. Women of child-bearing potential not using effective means of contraception

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	06-01-2007

Aantal proefpersonen:	864
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-03-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1172
NTR-old	NTR1217
Ander register	: NVALT 8A
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A