A randomized phase III study of adjuvant chemotherapy with or without low-molecular weight heparin in completely resected non-small-cell lung cancer patients with high-risk for recurrence: NVALT 8B

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Gives the addition of nadroparine during adjuvant chemotherapy in NSCLC a prolongation of the disease free survival?

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

Samenvatting

ID

NL-OMON24423

Bron
Nationaal Trial Register

Verkorte titel
NVALT 8B

Aandoening

Non-small-cell lung cancer

Ondersteuning

Primaire sponsor: UMCG
Hanzeplein 1
9700 RB Groningen
Overige ondersteuning: Pharmaceutical industry
Eli Lilly and GlaxoSmithKline’

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 high SUVof the primary tumor prior to surgery will be randomised to four cycles of pemetrexed and cisplatin with or without nadroparin for 16 weeks in order to improve the recurrence-free survival rate in these patients. A total of 600 patients will be entered in the study (300 patients in each arm) in 3 years. The follow up will continue for 2 years and 3 months further, at the end of which a total of 243 events would be observed allowing the comparison (alpha=0.05 two-sided log-rank test.) of the curves by treatment arm with 80% power to detect a true difference of 60% versus 70% at 3 years, or HR=0.70.

Doel van het onderzoek

Gives the addition of nadroparine during adjuvant chemotherapy in NSCLC a prolongation of the disease free survival?

Onderzoeksproduct en/of interventie

Within 4-6 weeks after surgery all patients will receive 4 cycles of pemetrexed (500 mg/m2) and cisplatin (75 mg/m2) on day 1 every 3 weeks. Patients in de nadroparin arm will receive nadroparin s.c. daily for 16 weeks, 2 weeks therapeutic dose en 14 weeks half-therapeutic dose.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

2. SUVmax >- 10

3. Patients with NSCLC who had a surgical R0 resection

4. Age > 18 years

5. WHO performance score <- 2 before chemotherapy

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 ULN, AP, ALT, AST <- 3.0 x ULN.

Renal: calculated creatinine clearance >- 60 ml/min based on the Cockroft and Gault formula.
INR< 1.5

7. Patients must sign and date a written independent Ethics Committee 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. Inability to interrupt aspirin or other nonsteroidal anti-inflammatory agents for a 5-day period (8 day period for long-acting agents such as piroxicam).

6. Inability or unwillingness to take folic acid, vitamin B-12 supplementation or dexamethasone.

7. 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.

8. Pregnancy

9. Men and women of child-bearing potential not using effective means of contraception for 6 months after treatment has been completed

10. Indication for anticoagulant treatment.

11. Any contraindication listed in the labeling of nadroparin.

12. Documented history of heparin-induced thrombocytopenia with UFH or LMWH

13. Current active bleeding or judged to be as high risk of bleeding;

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2007
Aantal proefpersonen:	600
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-03-2008
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	NL1205
NTR-old	NTR1250
Ander register	: NVALT 8-B
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A