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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24423

Source
NTR

Brief title
NVALT 8B

Health condition

Non-small-cell lung cancer

Sponsors and support

Primary sponsor: UMCG
Hanzeplein 1
9700 RB Groningen
Source(s) of monetary or material Support: Pharmaceutical industry
Eli Lilly and GlaxoSmithKline’

Intervention

Outcome measures

Primary outcome

The main endpoint is recurrence-free survival.

Secondary outcome

Secundary 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

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.

Study objective

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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;

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2007
Enrollment:	600
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-03-2008
Application type:	First submission

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
NTR-new	NL1205

Register	ID
NTR-old	NTR1250
Other	: NVALT 8-B
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A