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A prospective randomized study of adjuvant chemotherapy with navelbine and cisplatin in completely resected non small cell lung cancer

Submission date 01/03/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/03/2006	**Overall study status** Completed	
Last Edited 31/08/2011	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

PM25994 IN 303 J1

Study information

Scientific Title

Acronym
ANITA 01

Study objectives
Whether adjuvant chemotherapy improves survival of patients with non-small-cell lung cancer (NSCLC) is not known. We aimed to compare the effect of adjuvant vinorelbine plus cisplatin versus observation on survival in patients with completely resected NSCLC.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Consultative Committees for the Protection of Persons (Comités Consultatifs pour la Protection des Personnes [CCPPRB]) on 05/07/1994

Study design
Randomized, open, multicenter

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Non small cell lung cancer

Interventions
Chemotherapy with navelbine and cisplatin versus best supportive care.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Navelbine, cisplatin

Primary outcome measure
Primary endpoint is overall survival, one-sided test, alpha = 0.05, beta = 0.10, delta = 10%, anticipated two-year survival rate is 30%, benefit expected is an absolute improvement of 10% in the two-year survival rate.

Secondary outcome measures
1. To determine disease-free survival
2. To evaluate toxicity related to chemotherapy

Overall study start date
06/12/1994

Completion date
29/12/2000

Eligibility

Key inclusion criteria
1. Histologically proven primary non small cell lung cancer (NSCLC) (except bronchoalveolar carcinoma) stage I (T2N0 only), II, and IIIA according to the 1986 TNM classification
2. Complete resection of the primary tumor (all margins free of disease)
3. Age 18-75 years
4. World Health Organization (WHO) performance status ≤2
5. Adequate biological functions

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
840

Key exclusion criteria
1. Patients with a history of concurrent malignancy (except adequately treated non-melanoma skin cancer or in situ cervical cancer)
2. Previous treatment with adjuvant therapy

Date of first enrolment
06/12/1994

Date of final enrolment
29/12/2000

Locations

Countries of recruitment
Argentina

Austria

Brazil

Czech Republic

France

Greece

Italy

Lebanon

Poland

Portugal

Slovakia

South Africa

Spain

United States of America

Study participating centre
Chef du département d'Oncologie Médicale
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Sponsor information

Organisation
Pierre Fabre Oncologie (France)

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Sponsor type
Research organisation

ROR
https://ror.org/04hdhz511

Funder(s)

Funder type
Research organisation

Funder Name
Pierre Fabre Research Institute (Institut de Recherche Pierre Fabre) (france)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2006		Yes	No