

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
Registration date 22/03/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 31/08/2011	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomized, open, multicenter

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

75 Years

Sex

All

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

St-Herblain Cedex

France

44805

Sponsor information

Organisation

Pierre Fabre Oncologie (France)

ROR

<https://ror.org/04hdhz511>

Funder(s)

Funder type

Research organisation

Funder Name

Results and Publications

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