Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Randomized Phase II study of Vinorelbine Maintenance therapy vs Best Supportive Care in Advanced Non Small Cell Lung Cancer

Protocol summary

Summary

In this single blind, prospective, single institute , phase 2 and randomized trial, 100 patients with non small cell lung cancer (NSCLC)pathology, age >18 years, eastern cooperative oncology group (ECOG) performance statutes (PS) of 0-2, no pervious history of systemic chemotherapy and advanced stage (IIIB and IV) will be treated up to 6 cycles with Gemcitabine 1250 mg/m2 (day 1 and 8) plus Carboplatinarea under the concentration-time curve (AUC) 5 (day 1) every 3 weeks. Patients without progressive disease after first-line chemotherapy will be randomly assigned to receive switch maintenance with Vinorelbine (25mg/m2, day 1,15) or best supportive care until disease progression. Primary end point is progression free survival (PFS).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015060822610N1**
Registration date: **2016-08-17, 1395/05/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-08-17, 1395/05/27

Registrant information

Name

Adnan khosravi

Name of organization / entity

National institute of Tuberculosis and Lung Disease(NRITLD)

Country

Iran (Islamic Republic of)

Phone

+98 21 2610 9946

Email address

adkhosravi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2015-06-20, 1394/03/30

Expected recruitment end date

2017-06-20, 1396/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized Phase II study of Vinorelbine Maintenance therapy vs Best Supportive Care in Advanced Non Small Cell Lung Cancer

Public title

Meinetenance chemotherapy in lung cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria was: NSCLC pathology, age of 18 years or older, eastern cooperative oncology group (ECOG) performance statutes (PS) of 0-2, no pervious history of any systemic chemotherapy , advanced stage according AJCC, 7th editionat least one unidimensionally measurable or assessable disease, adequate bone marrow reserve, serum creatinine less than or equal to 1.5 mg/dL or a calculated creatinine clearance greater than or equal to 60 mL/min, bilirubin level less than or equal to 2.0 mg/dL, AST less than or equal to twice the institutional upper limits of normal and or less than or equal to four times the institutional upper limits of

normal if the patient had liver metastasis. Exclusion criteria was: administration of systemic chemotherapy, PS 3 and 4 , small cell lung cancer pathology,metastatic from other site,significant or uncontrolled cardiac, metabolic or infectious diseases and symptomatic brain metastasis.

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
randimization will be performed by using random number tables.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
ethics and scientific committees of National Institute of Tubercolusis and Lung Disease(NRITLD)

Street address
Dar Abad, Shaheed Bahonar Ave,

City
Tehran

Postal code

Approval date
2014-08-20, 1393/05/29

Ethics committee reference number
25/29/34562/پ

Health conditions studied

1

Description of health condition studied
Malignant neoplasm of lung and brochous

ICD-10 code
C 34

ICD-10 code description
Malignant neoplasm of bronchus and lung including: main bronchus, upper lobe bronchus , Middle lobe bronchus, Lower lobe, bronchus or Bronchus or lung, unspecified.code:C34

Primary outcomes

1

Description
Progression free survival

Timepoint
From date of registration to disease progression

Method of measurement
Time between date of registration to disease progression

Secondary outcomes

1

Description
Overall survival

Timepoint
From date of registration to disease progression

Method of measurement
Time between date of registration to disease progression

2

Description
Common Toxicity Critria

Timepoint
Before each chemotherapy course

Method of measurement
according to CTC version 3

Intervention groups

1

Description
Intervention group:Switch maintenance therapy with Novelbine (Vinorelbine tartrate, Pierre Fabre Pharmaceutical, Inc.) (25mg/m2, day 1,15) up to disease progression.

Category
Treatment - Drugs

2

Description
Control group: Best supoortive care untill disease progression.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
National Institute of Tuberculosis and Lung Disease (NRITLD), Masih Daneshvari Hospital
Full name of responsible person
Adnan Khosravi
Street address
DarAbad, Shahid Bahonar Ave.,
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Investigator
Full name of responsible person
Adnan Khosravi
Street address
Dar Abad, National Institute of Tuberculosis and Lung Disease
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Investigator
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
National Institute of Tubercolusis and Lung Disease(NRITLD)
Full name of responsible person
Adnan Khosravi
Position
M.D, Associated professor of medical oncology/ Head of NRITLD oncology department
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Tobacco Prevention and Control Research Center, National Research Institute of Tuberculosis and Lung
Full name of responsible person
Adnan Khosravi
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Person responsible for updating data

Contact
Name of organization / entity
National Research Institute of Tubercolusis and Lung Disease
Full name of responsible person
Adnan Khosravi
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Head of Hematology and oncology department/ M.D
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty