Chemotherapy in KRAS mutated chemotherapy naive non-small cell lung cancer patients: a phase III study comparing cisplatin-pemetrexed with carboplatin-paclitaxel-bevacizumab: NVALT 22

Published: 18-03-2016
Last updated: 19-04-2024

To compare two (standard) treatment regimens in patients with KRAS mutated advanced stage NSCLC as first line treatment.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON55867

Source
ToetsingOnline

Brief title
NVALT 22

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
Non-small cell lung cancer; KRAS mutation

Research involving
Human

Sponsors and support

Primary sponsor: Stichting NVALT studies
Source(s) of monetary or material Support: Eli Lilly,Roche,stichting NVALT (non-profit)

Intervention

Keyword: KRAS mutation, NSCLC, Phase III

Outcome measures

Primary outcome

To investigate in KRAS mutated patients with incurable NSCLC whether

carboplatin-paclitaxel-bevacizumab results in a prolonged progression free

survival compared to cisplatin-pemetrexed as first line treatment.

Secondary outcome

- To investigate differences in overall response rate (ORR) and disease control

rate

- To investigate differences in overall survival

- To investigate differences in outcome between different subtypes of KRAS

mutations

- To investigate response by Crabb criteria

Study description

Background summary

In a retrospective analysis of KRAS mutated non-small cell lung cancer (NSCLC) patients response and progression free survival to first line chemotherapy was better for carboplatin-paclitaxel-bevacizumab then other first line combinations.

Study objective

To compare two (standard) treatment regimens in patients with KRAS mutated advanced stage NSCLC as first line treatment.

Study design

A multicenter, randomized, open-label, phase III study in patients with KRAS mutated NSCLC receiving first line treatment. Patients will be randomized 1:1 to a standard and approved first line chemotherapy. Arm A: carboplatin AUC 6, paclitaxel 200 mg/m2, bevacizumab 15 mg/kg all administered intravenously on day 1 every 3 weeks for 4-6 cycles, followed by bevacizumab maintenance every 3 weeks until progression.
Arm B: pemetrexed 500 mg/m2, cisplatin 75 mg/m2 all administered intravenously on day 1 every 3 weeks for 4-6 cycles, followed by maintenance pemetrexed every 3 weeks until progression.

Intervention

Blood and archival tissue will be optionally collected (after consent of the patient) for translational research.

Study burden and risks

Both arms are standard of care first line treatments; no extra burden or risk for the patient.

Contacts

Public
Stichting NVALT studies

Luijbenstraat 15
's-Hertogenbosch 5211BR
NL
Scientific
Stichting NVALT studies

Luijbenstraat 15
's-Hertogenbosch 5211BR
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Histologically or cytologically confirmed NSCLC (Stage IIIB or IV)
Documented KRAS mutation
Chemotherapy-naive NSCLC patients
ECOG PS 0-2
Age 18 years or older
Adequate bone marrow, hepatic and renal function

Exclusion criteria

Pregnant or lactating women
Active cardiovascular disease
History of hemoptysis greater or equal to grade 2
Evidence of tumor invading major blood vessels on imaging

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-06-2016
Enrollment:	240
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Alimta
Generic name:	pemetrexed
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Avastin
Generic name:	bevacizumab
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	carboplatin
Generic name:	carboplatin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	cisplatin
Generic name:	cisplatin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Taxol
Generic name:	paclitaxel
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	18-03-2016
Application type:	First submission

Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	21-03-2016
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	23-06-2016
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	28-06-2016
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	06-09-2016
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	18-11-2016
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	25-11-2016
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	26-01-2017
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO	

Date:	01-02-2017
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	13-04-2017
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	20-04-2017
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	16-02-2018
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	26-02-2018
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	31-10-2018
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	15-11-2018
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	25-09-2019
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van

	Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	27-09-2019
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	29-09-2021
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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
EudraCT	EUCTR2015-003121-34-NL
ClinicalTrials.gov	NCT02743923
CCMO	NL52808.031.15