A Phase III, randomised trial of adding nitroglycerin to first line chemotherapy for advanced non-small cell lung cancer (NITRO TRIAL, NVALT-21 study)

Published: 09-07-2013
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To determine the efficacy and safety of adding transdermal nitroglycerin to first line chemotherapy for advanced NSCLC.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory tract neoplasms
Study type	Interventional

Summary

ID

NL-OMON38964

Source
ToetsingOnline

Brief title
NVALT21 NITRO TRIAL

Condition

- Respiratory tract neoplasms

Synonym
non-small cell lung cancer; NSCLC

Research involving
Human

Sponsors and support

Primary sponsor: Stichting NVALT studies
Source(s) of monetary or material Support: NVALT

Intervention

Keyword: advanced, nitroglycerin, NSCLC

Outcome measures

Primary outcome

Progression-free survival.

Secondary outcome

Overall survival, objective tumour response rates, adverse events, quality of

life.

Study description

Background summary

In this study the efficacy and safety of the addition of nitroglycerin patches to standard treatment with chemotherapy for advanced non-small cell lung cancer will be assessed. The objective of this treatment is to reduce the disease progression or to stop it temporarily.
Often there is a shortage of oxygen In the tumor. This stimulates the formation of new blood vessels in an attempt to increase the amount of oxygen in the tumor. This might counteract the efficacy of the chemotherapy.
Nitroglycerin (NTG) is a vasodilator. It might enhance the blood flow to the tumor en might thus reduce the lack of oxygen en reduce the stumulation of new blood vessel formation. This might be favorable for the treatment result. The vasodilation by NTG might also improve the accessibility of the tumor for chemotherapy. This might positively influence the effects of treatment. This study is being performed in order to evaluate whether the addition of NTG does indeed bring these beneficial effects.
NTG is already used for many decades as a medicine, mainly by the caridologist. It is not being used in the treatment of cancer. The drug has been approved (registered) by the Dutch authorities for the treatment of certain cardiac diseases.

Study objective

To determine the efficacy and safety of adding transdermal nitroglycerin to first line chemotherapy for advanced NSCLC.

Study design

Open, randomized phase III study. Treatment with standard chemotherapy. Choice by the treating physician:
1. Cisplatin plus vinorelbine
2. Carboplatin plus gemcitabine
3. Carboplatin plus paclitaxel
4. Cisplatin or carboplatin plus pemetrexed
Randomization to treatment with or without Transiderm-Nitro 5 (25 mg, 10cm2). The NTG patches will be used (during 12h per day) during every chemotherapy cycle during 5 days: from 2 days prior to the chemotherapy infusion day up to and including the second day after chemotherapy.
Treatment duration: as long as chemotherapy is continued. Follow-up for survival.

Intervention

Treatment with nitroglycerin patches.

Study burden and risks

Risk: Adverse events (mainly headache) of nitroglycerin.
Burden: In line with standard treatment with the following exceptions:
Diary for entering times of application and removal of NTG patches.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Stage III or IV non-small cell lung carcinoma. Measurable disease is not required.
2. ECOG performance status of 0, 1 or 2.
3. Radiotherapy completed at least 1 week before randomisation.
4. At least 18 years of age.
5. Adequate contraception for 30 days prior to drug administration for females of childbearing potential.

Exclusion criteria

1. Untreated brain or meningeal metastases.
2. Life expectancy less than 3 months.
3. Any prior systemic therapy for advanced NSCLC. Adjuvant chemotherapy for NSCLC completed more than 12 months before randomisation is allowed.
4. On nitrates, dihydroergotamine or phosphodiesterase inhibitors.
5. Uncontrolled cardiovascular disease.
6. Pregnancy, lactation.

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2013
Enrollment:	150
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Transiderm-Nitro 5
Generic name:	Nitroglycerin patch 25 mg 10cm2
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	09-07-2013
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	10-01-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	28-03-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	EUCTR2013-002050-78-NL
CCMO	NL45133.068.13
Other	Victorian Cancer Trials Link; ACTRN12608000588392