Prophylactic Cranial Irradiation (PCI) versus observation in radically treated patients with stage III non-small cell lung cancer: A phase III randomized study (NVALT-11/ DLCRG-02).

Published: 03-09-2008
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This randomized phase III study is designed to investigate whether PCI could reduce the incidence of brain metastases or delay their appearance in patients with stage III NSCLC who are treated with curative intention.

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

Summary

ID

NL-OMON35252

Source
ToetsingOnline

Brief title
NVALT-11/DLCRG-02

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Nederlandse Vereniging van artsen voor Longziekten en Tuberculose
Source(s) of monetary or material Support: Koningin Wilhelmina Fonds

Intervention

Keyword: cranial irradiation (PCI), non small cell lung cancer, prophylactic, radiotherapy

Outcome measures

Primary outcome

Patients will be followed for development of symptomatic brain metastases.

Secondary outcome

Secundary endpoints are: side effects, survival, quality of life (QLQ-C30 and

EuroQol 5D), quality adjusted survival (QALYs) and health care costs.

Study description

Background summary

At present brain metastases are one of the major sites of tumor failure in patients with stage III non-small cell lung cancer (NSCLC). Radical therapy of symptomatic brain metastasis is seldom possible and only very rarely, long-term survival can be achieved.
Prophylactic cranial irradiation (PCI) has been shown to reduce the incidence of brain metastases in patients with NSCLC to the same extent as in limited disease small-cell lung cancer. However, the exact value of PCI in properly staged III NSCLC patients, treated with contemporary chemoradiation schedules with or without surgery, remains unsettled.

Study objective

This randomized phase III study is designed to investigate whether PCI could reduce the incidence of brain metastases or delay their appearance in patients with stage III NSCLC who are treated with curative intention.

Study design

A total of 300 patients will be randomized in this study after radical

treatment receive to PCI or control. The PCI dose is left to the choice of the participating hospitals, either 36 Gy in 18 fractions, 30 Gy in 12 fractions or 30 Gy in 10 fractions. Patients will be registered into the study before randomizing, and patients progressing after the treatment for their lung cancer will not be randomized into the study. About 450 patients will be registered.

Intervention

The PCI dose is left to the choice of the participating hospitals, either 36 Gy in 18 fractions, 30 Gy in 12 fractions or 30 Gy in 10 fractions.

Study burden and risks

Standard side effects of cranial irradiation

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

4.1 Eligibility for registration
1. UICC stage III A or IIIB (without malignant pleural or pericardial effusion) non-small cell lung cancer (histology or cytology)
2. Whole body FDG-PET-scan before the start of therapy available: No distant metastases
3. CT or MRI of the brain before the start of therapy available: No brain metastases
4. No other malignancy in the preceding 2 years, except non-melanoma skin cancer or any carcinoma in situ.
5. No prior cranial irradiation
6 Patient should be suitable for radical treatment with Platinum-based chemotherapy and is planned to receive radical loco-regional therapy: concurrent or sequential chemotherapy (Platinum-based) and radiotherapy with or without surgery (Radiotherapy dose without surgery at least a biological equivalent of 60 Gy (20))
7. Patients must sign a study-specific informed consent at the time of registration. At the same time, thus before randomization, the baseline forms (CTCAE3.0, QLQ-C30 and EuroQol 5D) should be filled out.
8. Pregnant women are ineligible as treatment involves unforeseen risks to the participant and to the embryo or fetus; patients with childbearing potential must practice appropriate contraception
4.2 Conditions for Patient eligibility at randomization
1. Patient has been registered in the study and has completed appropriate radical treatment, no more than 6 weeks before. Registration is thus allowed either before or after radical therapy.
2 The patient is ready to receive PCI within 1 week of randomization (if randomized to PCI arm)
3. There is no clinical evidence of progressive disease after chemo-radiation (no imaging is requested)
4. No evidence of extracranial distant metastatic disease
5. Signed informed consent for randomization

Exclusion criteria

n.a.

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:	Completed
Start date (anticipated):	06-01-2009
Enrollment:	450
Type:	Actual

Ethics review

Approved WMO Date:	03-09-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	08-12-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	15-12-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	07-01-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit

	Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	12-01-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	30-01-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-02-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	08-04-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	15-05-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	29-06-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	10-08-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	16-10-2009

Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	07-12-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	16-12-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-06-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	02-07-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	02-05-2011
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
CCMO	NL23105.068.08

Study results

Date completed: 12-07-2019

Summary results
Trial ended prematurely