Cognitive sequelae of Prophylactic Cranial Irradiation in non-small cell lung cancer patients

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Ethical review	Approved WMO
Status	Pending
Health condition type	Neurological disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON33372

Source
ToetsingOnline

Brief title
cognitive problems after PCI for NSCLC

Condition

- Neurological disorders NEC

Synonym
cognitive dysfunction; problems with memory, learning and the ability to concentrate

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: door de deelnemende ziekenhuizen zelf

Intervention

Keyword: Cognition, neuropsychology, NSCLC, PCI

Outcome measures

Primary outcome

Performance on neuropsychological tests:

Rey Auditory Verbal Learning test, short form

Trailmaking A and B

Controlled Oral Word Association

Letter-number sequencing.

These neuropsychological tests are chosen based on the information of affected

functions by PCI, on their reliability and availability of Dutch norms.

An extra MRI scan

Secondary outcome

none

Study description

Background summary

Brain metastases are one of the major signs of failure in the treatment of patients with stage III non-small cell lung cancer (NSCLC). 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 stage III NSCLC patients, treated with contemporary chemo-radiation schedules with or without surgery, is unsettled.
A randomized phase III study is currently conducted to investigate whether PCI

should become the standard of care in patients with stage III NSCLC who are treated with curative intention. The hypothesis of this study is that PCI will prevent brain metastases, even for patients with other sites of failure, and that PCI will improve the neurological disease-free survival, and hence health-related quality of life (HRQOL).

From clinical observations can be learned that a subgroup of patients experiences adverse sequels. Observed symptoms include predominantly mental slowing and fatigue, interfering with daily life activities. The recent study of Slotman et al. (JCO 2009) confirms the occurrence of such adverse effects on cognitive functioning and other HRQOL parameters of PCI. Unfortunately, only short-term data were available in this study and conclusions could be drawn from patients* self-reported data only. To address cognitive functioning properly, objective testing by means of standardized neuropsychological tests is the method of choice in assessing neuropsychological problems, as self-reported cognitive complaints are clearly linked to and tend to reflect also other processes, such as depressive, anxiety or fatigue symptoms.

Study objective

The goal of PCI is to increase the neurological disease-free survival, without significant side effects, and hence to improve HRQOL.

This sub-study aims to investigate this expected advantage of PCI in NSCLC in maintaining function and increasing HRQOL by using all adequate measures to detect significant side effects, i.e. objective assessment of cognitive symptoms alongside self-reported symptoms and assessment of ADL function, in a large enough sample size with long-term follow-up data.

Study design

This neuropsychological sub-study is a longitudinal observational study in which NSCLC patients randomized to receive PCI or not will be followed over time.

Patients will be tested 5 times maximally:
1. At baseline (i.e. after radical treatment and after registration but before randomization to PCI or not)
2. 3 months after randomization of PCI
3. 6 months after randomization of PCI
4. 12 months after randomization of PCI
5. 24 months after randomization of PCI
Patients in the observation arm will be assessed at similar time interval.

The additional MRI scan performed for the purpose of the neuropsychological study will take place in the weeks preceeding the 12 months assessment point

randomization.

The neuropsychological assessment points coincide with the evaluations points in the main trial protocol.

Study burden and risks

Patients will be examined maximally 5 times over a period of 24 months. Each test assessment will last 15 minutes and consists of several neuropsychological tests. The additional neuropsychological examination does no pose any risk for patients. Ample experience with many patient populations has indicated that such a procedure is feasible and is not considered too burdensome. The addition MRI scan performed for the purpose of this study in the weeks before neuropsychological assessment at 12 months may elucidate the existence of a metastasis, that otherwise would potentially remain unnoticed for a given period of time. This early detection of brain metastasis could negatively impact the well-being of the patients and his/her significant others; on the other hand timely treatment could be offered at this stage.
Knowledge on the effects of PCI on cognitive functioning may aid to early detection of cognitive impairment and appropriate guidance of patients (and their relatives) confronted with such impairment and is essential in the discussion on the benefit of PCI.

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

- participating in the phase III trial: Prophylactic Cranial Irradiation (PCI) versus observation in radically treated patients with stage III non-small lung cancer: a phase III randomized study ((NVALT 11/DLCRG-02).
- sufficient proficiency in Dutch language
- MRI and not CT scan pre-PCI

Exclusion criteria

none

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-06-2009
Enrollment:	170
Type:	Anticipated

Ethics review

Approved WMO Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL27634.031.09