Fatigue after prophylactic cranial irradiation in stage I-III small cell lung cancer patients: is there a substrate on functional magnetic resonance imaging of the brain?

Published: 08-10-2014
Last updated: 19-03-2025

To asses the effect of PCI on the brain with functional MRI (fMRI) and diffusion tensor imaging (DTI)-MRI and assess whether there is a correlation with patient-experienced fatigue.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON41049

Source
ToetsingOnline

Brief title
fatigue after prophylactic cranial irradiation

Condition

- Other condition
- Respiratory tract neoplasms

Synonym
fatigue, small-cell lung cancer

Health condition

kleincellig longkanker patienten die profylactische schedelbestraling krijgen

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,nog geen subsidie. in gesprek met FHML voor subsidieregeling bij scannexus. Tevens subsidie aangevraagd bij lung cancer research group;tevens educational grant bij industrie (Pfizer) aangevraagd

Intervention

Keyword: fatigue, MRI, prophylactic cranial irradiation, small cell lung cancer

Outcome measures

Primary outcome

Changes in white matter integrity and bold response after PCI. Differences

between SCLC patients and controls for change in white matter integrity and

bold response.

Secondary outcome

- Relationship between changes in MRI parameters and changes in MVI-20, EORTC

c30, EuroQol-5D , HADS and CFQ

- Relationship between changes in MRI parameters and changes in IL-6, TNFα, CRP

and leukocytes/differential

Study description

Background summary

Cancer related fatigue (CRF) is a common problem in cancer patients. 50-90% of these patients report fatigue, the highest percentage is found in patients treated with chemo- and/or radiotherapy. Before starting cancer treatment, cancer patients already report fatigue and cognitive problems. Symptoms often worsen during and after treatment.
CRF may represent imbalances in inflammatory and inhibitory mechanisms induced

by cancer and/or chemo- and radiotherapy. For example, in some studies elevated levels of fatigue have been reported in association with increased serum measurements of pro-inflammatory cytokines like IL-6 and TNF-α. The hypothesis is that these cytokines cause alterations in the central nervous system (CNS) promoting fatigue. Recently, researchers started to investigate organic substrate in fatigue using functional and structural magnetic resonance imaging (MRI) of the brain as well in non-oncological as oncological patients. Fatigue was linked with regions of decreased frontal and basal ganglia perfusion. MRI is more sensitive in detecting functional differences than behavioural measurements alone. Prophylactic cranial irradiation (PCI) is standard treatment in small cell lung cancer (SCLC) patients with response or stable disease after first line treatment (chemoradiotherapy in stage I-III, chemotherapy in stage IV). These patients report in the first 3 months after PCI significantly more fatigue than patients who have not had PCI, but there are not many data regarding MRI and PCI. In this pilot study we want to evaluate whether there is a substrate for fatigue on MRI and whether there is a correlation with pro-inflammatory cytokines.

Study objective

To asses the effect of PCI on the brain with functional MRI (fMRI) and diffusion tensor imaging (DTI)-MRI and assess whether there is a correlation with patient-experienced fatigue.

Study design

prospective study

Study burden and risks

The MRI-techniques and questionnaires that are used in this study are non-invasive. The risks of a MRI-scan are negligible because it is a magnetic field, does not involve ionizing radiation and does not require contrast agents or anesthesia.
The MRI will be performed twice, preferably the same day as when a regular visit to the radiation oncologist is scheduled. Time per MRI is approximately 30 minutes. The MVI-20, EORTC c30 and EuroQol 5D questionnaires are validated in cancer patients, duration per set of questionnaires is approximately 5 minutes. Screening for depression (HADS) and cognitive failure (CFQ) will also be done (duration per questionnaire approximately 5 minutes). These questionnaires will be taken at the same day as the MRI. All questionnaires will also be taken at baseline; baseline also includes a personality test (NEO-FFI, duration 10 minutes). Blood samples will be withdrawn twice, total amount is 20 ml. There is no direct benefit for the patient. This is a study to evaluate the usefulness of MRI in fatigue after PCI in order to incorporate

this assessment in intervention studies.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

P Debijelaan 25
Maastricht 6229HX
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

P Debijelaan 25
Maastricht 6229HX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Stage I-III SCLC:
- Age >= 18 years
- stage I-III SCLC pathology proven
- Completed initial treatment with chemoradiotherapy, with at least stable disease (SD)
- WHO PS <= 2
- Ability to understand written questionnaires
- Written informed consent;Stage III NSCLC:
- Age >= 18 years
- stage I-III NSCLC pathology proven

- Completed treatment with chemoradiotherapy, with at least SD
- WHO PS <= 2
- Ability to understand written questionnaires
- Written informed consent;Healthy controls:
- Age >= 18 years
- WHO PS <= 2
- Ability to understand written questionnaires
- Written informed consent

Exclusion criteria

- prior radiotherapy to the brain
- claustrophobia
- pregnancy
- Metal implants or other contraindication for MRI
- inability to lie supine for 30 minutes time (MRI)
- antidepressants or steroids for the last two weeks
- clinically relevant anemia (defined as Hb < 5.5 mmol/l)
- chronic renal failure (defined as MDRD-eGFR < 30 ml/min/1.73m)
- liver biochemistry abnormalities (defined as more than two times upper limit of normal)
- major psychiatric illness requiring intervention in secondary care

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-06-2016
Enrollment:	46

Type:	Actual

Ethics review

Approved WMO Date:	08-10-2014
Application type:	First submission
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

ID: 29029
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	aangemeld NTR, nummer volgt
CCMO	NL48269.068.14
OMON	NL-OMON29029