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?

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29029

Bron
NTR

Verkorte titel
fatigue, prophylactic cranial irradiation, small cell lung cancer, MRI

Aandoening

fatigue, prophylactic cranial irradiation, small cell lung cancer, MRI
vermoeidheid, profylactische schedelbestraling, kleincellig longcarcinoom, MRI

Ondersteuning

Primaire sponsor: AzM
PO Box 5800 6202 AZ Maastricht
The Netherlands
Overige ondersteuning: applications for funding running, at the moment no funding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: 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-¦Á. 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.

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 population: 22 stage I-III SCLC patients who have completed chemoradiation and are eligible for PCI. Control groups: 12 stage III non-small cell lung cancer (NSCLC) patients who have completed chemoradiation, 12 matched (age, gender, smoking status) healthy individuals.

Intervention: MRI will be performed approximately one week before PCI and two weeks after PCI. Blood samples will be drawn on the same day as the MRI. Fatigue and quality of life will be measured with questionnaires (MVI-20, EORTC c30, EuroQol-5D) on the same day as the MRI. Screening for depression (HADS), cognitive failure (CFQ) will also be done on the same days. The day of the first MRI also includes a personality test (NEO-FFI).

Main study parameters/endpoints: 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.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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. The first time the questionnaires also include 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.

Doel van het onderzoek

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.

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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

Onderzoeksproduct en/of interventie

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Contactpersonen

Publiek

Dept of Pulmonary Diseases, MUMC+
PO Box 5800
L. Hendriks
Maastricht 6202 AZ
The Netherlands
+31 (0) 43 387 6543

Wetenschappelijk

Dept of Pulmonary Diseases, MUMC+
PO Box 5800
L. Hendriks
Maastricht 6202 AZ
The Netherlands
+31 (0) 43 387 6543

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2015
Aantal proefpersonen:	46
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-10-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41049
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4683
NTR-old	NTR4837
CCMO	NL48269.068.14
OMON	NL-OMON41049

Resultaten