‘Saving the brain’

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24435

Bron
NTR

Verkorte titel
TBA

Aandoening

Head-neck cancer

Ondersteuning

Primaire sponsor: Medical Imaging Center, UMCG
Overige ondersteuning: ZonMw VENI (file number 09150161910041)
King Saud University, Riyadh, Saudi Arabia, Ministry of Education, Saudi Arabia, Saudi Cultural Bureau, Netherlands.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The occurrence, location and appearance of brain microvascular and white matter radiotherapy-induced changes on sequentially obtained MRI & PET images performed in

several time points in comparison with the baseline MRI and PET images and conventional MRI images.

Toelichting onderzoek

Achtergrond van het onderzoek

Radiotherapy-induced brain injury can clinically manifest as cognitive decline and neurobehavioral impairment and is considered irreversible in the chronic phase, affecting patients' quality of life [1][2]. The suspected mechanisms of cognitive decline seem to be complex and probably triggered by early microvascular damage causing disruptions in blood flow and improper blood-brain barrier function, loss and dysfunction of oligodendrocytes, damage and dysfunction of astrocytes, delayed neurogenesis, inflammation, neurodegeneration and microanatomical abnormalities and therefore, neuronal dysfunction [3]. Cognitive decline occurs within months or years after radiotherapy [1-3]. So far, no validated imaging tools are available for assessing the risks of acute and/or chronic brain damage caused by radiotherapy. Several MRI techniques, such as Susceptibility Weighted Imaging (SWI), Quantitative Susceptibility Mapping (QSM), vessel architectural imaging (VAI), Arterial Spin Labelling (ASL), Synthetic MRI (synMRI) and Diffusion Kurtosis Imaging (DKI) have the potential to visualize microvascular changes and white matter changes, especially when combining findings of several individual approaches. Furthermore, metabolic brain changes, neuroinflammation and neurodegeneration can be monitored by respectively [18F]FDG PET, [11C]UCB-J PET and [11C]PK11195 PET.
Therefore, in this pilot study we want to look at different aspects of radiation damage, including effects on microvasculature, blood-brain barrier function and white matter changes. We hypothesize that combining these different imaging modalities (MRI and PET) with advanced post-processing will increase the understanding of in vivo changes resulting from radiotherapy-induced injury and will allow the detection of radiotherapy-induced brain injury at an early stages. We also hypothesize that early detection of changes (or lack thereof) will be predictive of (later) cognitive outcome assessed by neurocognitive function test.

Doel van het onderzoek

In this pilot study we want to look at different aspects of radiation damage, including effects on microvasculature, blood-brain barrier function and white matter changes. We hypothesize that combining these different imaging modalities (MRI and PET) with advanced post-processing will increase the understanding of in vivo changes resulting from radiotherapy-induced injury and will allow the detection of radiotherapy-induced brain injury at an early stages. We also hypothesize that early detection of changes (or lack thereof) will be predictive of (later) cognitive outcome assessed by neurocognitive function test.
Primary Objective: Is detection of the early brain changes, including microvascular and white matter radiotherapy-induced changes, possible already during radiotherapy treatment by means of combining novel MRI and PET techniques and post-processing methods in patients treated for head and neck tumours.

Onderzoeksopzet

The study will consist of 5 visits:
- baseline visit within 2 weeks before the start of radiotherapy (clinical-research visit combined)
- 2 weeks after the beginning of radiotherapy (research visit only)
- directly after the end of radiotherapy (research visit only)
- 3 months after the end of radiotherapy (clinical-research visit combined)
- 1 year after the end of radiotherapy (clinical-research visit combined)

Onderzoeksproduct en/of interventie

not applicable

Contactpersonen

Publiek

UMCG
Anouk van der Hoorn

0625650171

Wetenschappelijk

UMCG
Anouk van der Hoorn

0625650171

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

 adults (18-70 years),
 referred for treatment of tumours located in nasopharynx, oropharynx and sinonasal cavity with radiotherapy (photons or protons), with or without systemic treatment, with a close proximity of 1.5 cm of the clinical target volume (CTV elective dose) to the brain or brainstem.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

 age <18 or > 70 years old at baseline;
 brain neurological disease other than consequences of head and neck cancer and its treatment (like a stroke);
 history of psychiatric disease;
 history of chemotherapy or radiotherapy for other tumours;
 chronic treatment with verapamil at baseline;
 pregnancy;
 contradictions for performing MRI, such as non-MRI compatible heart pacemaker, metallic foreign body in the eye, aneurysm clip in the brain or claustrophobic patient;
 contrast allergies.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2021
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9548
Ander register	METC Groningen : Follows

Resultaten