'Saving the brain'

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24435

Source NTR

Brief title TBA

Health condition

Head-neck cancer

Sponsors and support

Primary sponsor: Medical Imaging Center, UMCG **Source(s) of monetary or material Support:** ZonMw VENI (file number 09150161910041) King Saud University, Riyadh, Saudi Arabia, Ministry of Education, Saudi Arabia, Saudi Cultural Bureau, Netherlands.

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Is there an association between the early brain damage demonstrated with MRI and PET imaging with the subsequent occurrence later brain damage on MRI and PET and cognitive and neurobehavioral changes in patients treated for head and neck tumours? Have patients that received proton therapy less brain damage than patients with photon therapy?

Study description

Background summary

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.

Study objective

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 postprocessing will increase the understanding of in vivo changes resulting from radiotherapyinduced 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.

Study design

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)

Intervention

not applicable

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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.

Study design

Design

Study type:	Observational non invasive	
Intervention model:	Other	
Allocation:	Non controlled trial	
Masking:	Open (masking not used)	
Control:	N/A , unknown	

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2021
Enrollment:	40
Туре:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable Application type:

Not applicable

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

RegisterIDNTR-newNL9548OtherMETC Groningen : Follows

Study results