PREselection of patients at risk for COgnitive DEcline after Radiotherapy using advanced MRI (PRECODE-MRI)

Published: 12-02-2021
Last updated: 08-04-2024

To investigate the dose-response relation between cognitive decline and radiotherapy dose for patients with a benign meningioma WHO I.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Nervous system neoplasms benign
Study type	Observational non invasive

Summary

ID

NL-OMON52049

Source
ToetsingOnline

Brief title
PRECODE-MRI

Condition

- Nervous system neoplasms benign
- Nervous system neoplasms benign

Synonym
benign, brain tumour, Meningioma

Research involving
Human

Sponsors and support

Primary sponsor: MAASTRO clinic

Source(s) of monetary or material Support: NWO / ZONMW;programma topspecialistische zorg en onderzoek (TZO)

Intervention

Keyword: Meningioma, MRI, Neurocognition, Radiotherapy

Outcome measures

Primary outcome

Correlation between the delta cognitive failure score (baseline vs 2 years) and radiotherapy dose in cognition related brain regions (supratentorial brain, hippocampus left/right and anterior/posterior, cerebellum anterior/posterior).

Secondary outcome

- Correlation between baseline imaging (advanced MRI sequence) and patient specific parameters (e.g. baseline cognitive status, age, Karnofsky index (KPS), co-morbidity, alcohol consumption, smoking, medication)
- RT-induced cognitive decline measured with extensive cognitive testing; specifically looking at: Hopkins verbal learning (HVLT), Trail making test A & B, COWA, Digitspan, LDST, Stroop, Fluency, Dutch wordlist/NLV (IQ-score)
- Correlation of advanced MRI and treatment/dose parameters to PROMS; EQ/5D, QLQ/C30, QLQ/BN20, Cognitive Failure questionnaire (CFQ) , Multidimentional Fatigue Index (MVI/20)
- Identification of radiation susceptibility of individual anatomical and functional central nervous system (CNS) organs (e.g. (hippocampi, frontal lobe, cerebellum, brain) for radiation damage;
- Sensitivity of additional extensive neurocognitive tests.
- Correlation of advanced MRI and treatment/dose parameters and radiotherapy

modality (photon vs proton)

Study description

Background summary

Meningioma are slow growing and frequently occurring intracranial tumors, responsible for 33% of all asymptomatic intracranial tumors and 13-26% of all symptomatic primary brain tumors1,2. The 10-year survival rate is 72%. 3 A variety of treatment options is available for symptomatic meningioma including surgical removal with or without radiotherapy or radiotherapy alone. These therapies can have negative impact on cerebral functioning.

After high dose radiotherapy for primary or metastatic brain tumors 50-90% of > 6 months* survivors develop irreversible disabling cognitive decline leading to premature loss of independence, reduced Quality of Life (QOL) as well as significant economic burden both at the individual as societal level6. Especially for patients with a good prognosis like benign meningioma, maintaining neurocognitive function is crucial. Understanding the mechanisms underlying radiation induced cognitive decline is complex and which brain areas to spare are an important subject of research9,10.

Evaluation methods to assess cognitive function and predict cognitive decline are urgently needed, this will allow the development of optimized treatment strategies with the aim to preserve or even improve cognitive function in meningioma patients. Improvements in the field of neuroimaging techniques (i.e. advanced MRI techniques) have the possibility to identify areas susceptible to cognitive impairment. This allows in the future a more personalized radiation treatment by identifying patients at risk, by optimizing the radiotherapy dose to specific brain regions, that could eventually reduce or prevent, cognitive decline. Improvements in the field of radiotherapy for example by higher precision treatment such proton therapy have potential in obtaining these more individualized strategies

Study objective

To investigate the dose-response relation between cognitive decline and radiotherapy dose for patients with a benign meningioma WHO I.

Study design

The study is designed as a prospective observational cohort study: patients with meningioma WHO I tumours treated with radiotherapy will be included, undergoing extensive cognitive testing combined with advanced brain MRI scans

just before, 3 and 24 months after radiotherapy.

Study burden and risks

The study is non-interventional, we do not expect any risks or benefits for the patients. The burden related to the completion of additional questionnaires, neuro-cognitive testing and advanced MRI acquisition is considered low. There is no individual patient benefit, nevertheless the study will provide new insights and knowledge to improve the radiation treatment of similar patients in the future.

Contacts

Public
MAASTRO clinic

Dr. Tanslaan 12
Maastricht 6229ET
NL
Scientific
MAASTRO clinic

Dr. Tanslaan 12
Maastricht 6229ET
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Meningioma WHO I, grading based on pathology or radiological features
- Age >= 18 years.
- Karnofsky Performance Score 70 or above.
- Ability to comply with the protocol, including neuropsychological testing and imaging.
- Ability to understand the requirements of the study and to give written informed consent, as determined by the treating physician.
- Written informed consent.

Exclusion criteria

- Resection meningioma < 3mnd
- Age < 18 years
- Pregnancy
- Any prior cranial radiotherapy
- Any prior chemotherapy in the last 5 years
- Contra-indication for MR imaging (i.e. metal implants, claustrophobia)
- Any other serious medical condition that could interfere with follow-up.
- Severe aphasia or language barrier interfering with assessing endpoints (i.e. completion of questionnaires or neurocognitive performance)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-04-2021
Enrollment:	67
Type:	Actual

Ethics review

Approved WMO Date:	12-02-2021
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

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT04638478
CCMO	NL75632.068.20