The long-term impact of immunotherapy and targeted therapy on outcomes in patients with brain metastases

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To determine outcomes in long-term surviving brain metastases patients (>=2 years after diagnosis of brain metastases) treated with immunotherapy or targeted therapy.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Metastases
Study type	Observational non invasive

Summary

ID

NL-OMON53728

Source
ToetsingOnline

Brief title
LFUBM

Condition

- Metastases
- Nervous system neoplasms malignant and unspecified NEC

Synonym
Brain metastases; Cancer that has spread to the brain

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: het onderzoek wordt uitgevoerd door onderzoekers die reeds op andere subsidies zitten;en/of studenten Geneeskunde

Intervention

Keyword: Brain metastases, Health-related quality of life, Long term outcomes, Neurocognition

Outcome measures

Primary outcome

- Neurocognitive functioning

- Instrumental activities of daily living

- Health-related quality of life

- Epilepsy

- Radiological abnormalities (cerebral abnormalities and treatment-induced radiological abnormalities)

Secondary outcome

Sociodemographic information (i.e. age at study assessments, gender, level of education, marital status and living arrangements, current or last profession) and clinical information (Karnofsky Performance Status, date of diagnosis primary cancer, relevant histological and molecular tumor information, sites of metastases, date of diagnosis brain metastases, number and location of brain metastases, previously received anti-tumor treatment and anti-tumor treatment at assessment, corticosteroid and antiepileptic drug use, and comorbidity).

Study description

Background summary

While prolonged survival can be achieved for patients with brain metastases from any stage IV solid primary cancer treated with newer treatments such as immunotherapy and targeted therapy, information on the impact of these

treatments on different outcomes, including those relevant to patients such as the level of functioning and well-being, is scarce.

Study objective

To determine outcomes in long-term surviving brain metastases patients (>=2 years after diagnosis of brain metastases) treated with immunotherapy or targeted therapy.

Study design

This will be a multicenter cross-sectional study on the long-term outcomes of brain metastases patients treated with immunotherapy or targeted therapy.

Study burden and risks

While prolonged survival can be achieved for patients with brain metastases treated with newer treatments such as immunotherapy and targeted therapy, information on the impact of these treatment on different outcomes, including those relevant to patients such as the level of functioning and well-being, is scarce. This study will provide information about the net clinical benefit of certain treatment strategies for patients with brain metastases, which can be used in clinical decision-making. Although the included patients will not benefit from this knowledge themselves, the results are valuable for future patients. The risk and burden of this study for the participating patients is minimal, although filling in the questionnaires and undergoing the neurocognitive tests may be perceived as tiresome for some patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Any histologically confirmed stage IV solid primary cancer and radiologically confirmed brain metastases;
- Adult patients: >=18 years of age;
- Treated with immunotherapy and/or targeted therapy (as monotherapy, combined or in combination with other treatment modalities);
- Diagnosis of brain metastases >=2 years ago;
- Willing to provide written informed consent.

Exclusion criteria

- Patients without understanding of the Dutch language, hampering the completion of questionnaires or undergoing neurocognitive testing;
- Patients with a poor physical condition or any psychiatric condition or cognitive impairment, as determined by the treating physician, that will hamper them to provide consent to research or undergo neurocognitive testing or completion of the questionnaires.

Study design

Design

Study type: Observational non invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-10-2023
Enrollment:	72
Type:	Actual

Ethics review

Approved WMO Date:	01-05-2023
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	11-12-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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
CCMO	NL81888.058.22