The Cohort for patient-reported Outcomes, Imaging and trial inclusion in Metastatic BRAin disease

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1) To collect information on patient characteristics, short and long-term clinical and patient reported outcomes and those of his/her caregiver. 2) To evaluate feasibility, performance and added value of new magnetic resonance imaging (MRI)...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Nervous system neoplasms malignant and unspecified NEC
Study type	Observational invasive

Summary

ID

NL-OMON52435

Source
ToetsingOnline

Brief title
COIMBRA

Condition

- Nervous system neoplasms malignant and unspecified NEC
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Synonym
Brain metastases, metastatic brain disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Brain metastases, cmRCT, Cohort, Patient-reported outcomes

Outcome measures

Primary outcome

Clinical parameters (co-morbidity, oncological history, symptoms, imaging, technical and treatment data), clinical endpoints (toxicity, reintervention and survival) and patient reported outcomes.

Secondary outcome

Not applicable.

Study description

Background summary

The incidence of brain metastases is expected to increase because of better treatments of primary tumours. Novel diagnostic and therapeutic techniques are continuously being developed, all of which need thorough evaluation before they can be implemented in clinical routine. Randomized Controlled Trials are the gold standard to do so, but they have shown many challenges, especially when applied in a cancer setting. The *cohort multiple Randomized Controlled Trial (cmRCT)* design is a promising design for multiple (simultaneous) randomized evaluations of experimental interventions, with potential for increased recruitment, comparability and long-term outcomes as a standard. This design will speed up the process of translating treatment innovations to the daily clinic.

Study objective

1) To collect information on patient characteristics, short and long-term clinical and patient reported outcomes and those of his/her caregiver.
2) To evaluate feasibility, performance and added value of new magnetic resonance imaging (MRI) techniques.
3) To create an infrastructure for efficient, fast and pragmatic randomized evaluation of new interventions.

Study design

Observational, prospective cohort study, according to the *cohort multiple Randomized Controlled Trial* (cmRCT) design.

Study burden and risks

Patients will not experience direct benefit from participation in the COIMBRA cohort. By participating, patients will contribute to the evidence on clinical and environmental factors associated with treatment outcome, quality of life (QoL) and survival. This will lead to better and a more personalized cancer care for future patients. When not participating in RCT's, patients will receive the regular optimal clinical care. Risks associated with participating in the COIMBRA cohort study are negligible since it is an observational study. Filling out the questionnaires, and the extra time in the MRI-scanner are the only potential burden for the patients participating in this cohort. It will take approximately 20-35 minutes to fill out the questionnaires each time. It takes approximately 10 minutes for the caregiver to complete the questionnaire each time. Finally, performing the NCA lasts, three times 90 minutes

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

- Age >= 18 years;
- Either radiographic and/or histologic proof of metastatic brain disease, or eligible for prophylactic cranial irradiation;
- Referred to the Department of Radiotherapy for cranial irradiation.

Exclusion criteria

- Mental disorder or cognitive dysfunction that hinder the patient*s ability to understand the informed consent procedure and/or study details;
- Patients with severe psychiatric disorders;
- Inability to understand the Dutch language.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-04-2019
Enrollment:	2000
Type:	Actual

Ethics review

Approved WMO Date:	12-12-2018
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	17-06-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-09-2022
Application type:	Amendment
Review commission:	METC NedMec

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	NL67206.041.18