Improving therapeutic ratio with hypofractionated stereotactic radiotherapy for brain metastases.

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To determine if the incidence of adverse local events (local failure or radionecrosis) can be reduced with more than 20% using fSRT versus SRT in one or three fractions.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Metastases
Study type	Interventional

Summary

ID

NL-OMON56002

Source
ToetsingOnline

Brief title
SAFESTEREO

Condition

- Metastases
- Nervous system, skull and spine therapeutic procedures

Synonym
brain metastasis; cancer spread in the brain

Research involving
Human

Sponsors and support

Primary sponsor: Haaglanden Medisch Centrum
Source(s) of monetary or material Support: St. Jacobus Stichting

Intervention

Keyword: brain, hypofractionation, metastases, radiotherapy

Outcome measures

Primary outcome

The main study parameter is the incidence of adverse local event (either

radionecrosis or local failure according to RANO) at 2 year post-radiotherapy

with respect to baseline

Secondary outcome

- Survival

- Quality of life

- Seizure outcome

- Toxicity

Study description

Background summary

Stereotactic radiotherapy is one of the most frequently chosen treatment options for brain metastases. There are an increasing number of long term survivors. Brain necrosis (e.g. radionecrosis) is the most important long term side effect of the treatment, occurring in up to 40% of patients, dependent on the size of the metastasis and delivered radiotherapy dose. Retrospective studies have shown that the incidence of radionecrosis, as well as local tumor recurrence, can be decreased with a risk difference of around 20% by administrating fractionated stereotactic radiotherapy (fSRT, e.g. five fractions) over single fraction stereotactic radiotherapy, especially in large brain metastases.

Study objective

To determine if the incidence of adverse local events (local failure or radionecrosis) can be reduced with more than 20% using fSRT versus SRT in one

or three fractions.

Study design

Prospective cohort study with two cohorts. Randomized study with two randomization arms. Patients are randomly placed in one of the two groups .

Intervention

One group is treated with SRT in one or three fractions. The other group is treated with fSRT in five fractions.

Study burden and risks

The study aims to investigate a different and potentially safer treatment method than the current standard of care. It is unlikely that the risk of adverse events will be increased in the experimental cohort compared to the standard cohort. The additional burden as a result of study participation consists of the following: between two and four additional site visits for treatment in the experimental group; a total of eighteen (facultative) questionnaires spread throughout the follow-up period.

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
- At least one brain metastasis of large cell cancer suitable for SRT
- Karnofsky Performance Status >= 70
- Ability to provide written informed consent
- Previous systemic therapy for brain metastases allowed
- New brain metastases during follow-up after surgery allowed (outside resection cavity)

Exclusion criteria

- Contra-indication for MRI scan
- Primary tumor of small cell lung cancer, germinoma or lymphoma
- Prior whole brain radiotherapy or SRT on the current target brain metastases (BM) (in field re-irradiation; salvage SRT of non-irradiated BM allowed if radiation dose from previous irradiation in current target field is <1.0 Gy)
- The presence of leptomeningeal metastases
- Previous inclusion in the SAFESTEREO study
-Active bleeding metastases

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-07-2022
Enrollment:	130
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	17-01-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	08-06-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	17-10-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	20-04-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	15-12-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	31-05-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	08-07-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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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	NCT05346367
CCMO	NL77876.058.21