# Radiotherapy of the head without the need of a thermoplastic mask, a clinical feasibility study.

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To prove the clinical feasibility of palliative whole brain radiotherapy without using a thermoplastic mask. Clinical feasibility in this study is defined when more than 70% of the patients can complete the radiation treatment without a mask. We...

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| **Ethical review** | Approved WMO |
| **Status** | Completed |
| **Health condition type** | Metastases |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON44293

**Source**
ToetsingOnline

**Brief title**
Irradiation without mask.

### Condition

- Metastases

**Synonym**
'brain metastasis', 'brain tumor'

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Dr. Bernard Verbeeten Instituut
**Source(s) of monetary or material Support:** deels door fondswerving van Stichting Verbeeten Fonds en deels door Instituut Verbeeten.

## Intervention

**Keyword:** Intra-fraction motion, Optical surface scanning, Radiotherapy, Real-time monitoring

## Outcome measures

### Primary outcome

Rate of success of the treatment.

### Secondary outcome

- Intra-fractional movement: the total amount of movements of the head during a

fraction, detected by a surface scanner .

- Intra-fractional position: difference between the position at the start and

the end of a fraction

- MV-cine imaging: movement of the head during a fraction.

# Study description

### Background summary

During radiation of the brain, a thermoplastic mask is used to fixate the head, preventing movements during the treatment. However, many patients complain about the tightness and experience discomfort. Therefore, a treatment method without the necessity of a head mask is of advantage for patients. An optical surface scanner can be used as a movement monitoring tool during radiation therapy of the head. We will evaluate whether stabilization of the back of the head is sufficient, such that movement is minimized, which is needed for whole brain radiotherapy.
Based on literature we expect patients to be able to lie still during the treatment. With sufficient support of the head and by using an optical surface scanner, we expect a mask is not necessary.

### Study objective

To prove the clinical feasibility of palliative whole brain radiotherapy without using a thermoplastic mask. Clinical feasibility in this study is defined when more than 70% of the patients can complete the radiation treatment

without a mask. We suppose a failure of less than 30% to be acceptable for both patients and clinicians. A complete treatment consists of five fractions. The treatment is considered to be successful when three or more fractions of one patient have been successful. A fraction is defined to be successful if no more than two times a session, repositioning is needed.

### Study design

The study is a clinical feasibility study. All subjects participating in the study receive whole brain radiotherapy without using a thermoplastic mask.

### Intervention

The intervention in this study concerns the treatment method of whole brain radiotherapy; the treatment itself is the same whether patients participate in the study or not. Patients are instructed to lie as still as possible on the treatment table and not to move their head during the radiotherapy treatment. As is common with radiotherapy of the head, online imaging is used for a reproducible inter-fractional position of the head. For movement detection during the treatment an optical surface scanner is used. The surface scanner used for this study is the Catalyst* (C-RAD AB, Sweden), which constructs a 3D-reconstruction of a subject. The actual position of the patient is compared to a daily made reference image and the deviation is presented on a screen. If it becomes clear a patient is not able to lie still, the treatment can be continued by using a mask.

### Study burden and risks

If the movement of the head exceeds the threshold, the radiation is temporary stopped. The technologist repositions the patient and the radiation continues. The treatment can in any case be continued using a mask during the next fraction. Therefore, an unsuccessful treatment method has no consequences for the effectiveness of the radiotherapy for the patient.

## 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

- The therapy is aimed to be palliative and consists of whole brain radiation therapy, 5x4 Gy.
- The patient is motivated and willing to be involved in radiotherapy without a mask.
- According to the impression of the radiation oncologist, the patient is able to lie still during the treatment.
- The patient is competent enough to understand the Dutch language to follow up instructions of the radiation technologist.

## Exclusion criteria

Suffering from trembling or shaking of the head, for example caused by Parkinson*s disease.

# Study design

## Design

**Study type:** Interventional

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |

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| Primary purpose: | Treatment |

### Recruitment

NL

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| Recruitment status: | Completed |
| Start date (anticipated): | 25-10-2017 |
| Enrollment: | 30 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Generic name: | Catalyst |
| Registration: | Yes - CE intended use |

## Ethics review

Approved WMO

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|---|---|
| Date: | 12-07-2017 |
| Application type: | First submission |
| Review commission: | METC Brabant (Tilburg) |

Approved WMO

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|---|---|
| Date: | 13-09-2017 |
| Application type: | Amendment |
| Review commission: | METC Brabant (Tilburg) |

## 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 | NL61854.028.17 |

# Study results

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| --- | --- |
| Date completed: | 02-10-2018 |
| Results posted: | 13-08-2019 |
| Actual enrolment: | 30 |

**First publication**
25-07-2019