# Inter- and intra-fraction fiducial position reproducibility in end-exhalation breath hold for Ethos liver radiotherapy

Published: 23-10-2024
Last updated: 18-01-2025

To determine inter- and intra-fraction fiducial and patient position reproducibility in order to determine appropriate safety margins for liver SBRT treatment on Ethos.

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Hepatobiliary neoplasms malignant and unspecified |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON57145

**Source**
ToetsingOnline

**Brief title**
Part of the Modern Art study

### Condition

- Hepatobiliary neoplasms malignant and unspecified

**Synonym**
hepatocellular carcinoma, liver metastases

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam
**Source(s) of monetary or material Support:** Varian Medical Systems

## Intervention

**Keyword:** Hepatocellular carcinoma, Liver metastases, Online adaptive, Stereotactic body radiation therapy

## Outcome measures

### Primary outcome

The primary parameters are inter- and intra-fraction fiducial position

reproducibility on the Ethos.

### Secondary outcome

not applicable.

# Study description

### Background summary

One of the possible treatments for patients with liver tumours (hepatocellular carcinoma (HCC) or liver metastases) at the Erasmus MC is stereotactic body radiation therapy (SBRT) on the Cyberknife. To spare the organs at risk, suboptimal coverage of the planning target volume is sometimes accepted on the Cyberknife. The Ethos treatment system is equipped with a novel cone-beam CT (CBCT), which provides higher quality images. This makes it possible to consider online adaptive radiotherapy with daily plan adaptation, potentially leading to a higher dose on the tumour whilst sparing the surrounding healthy tissue more.

### Study objective

To determine inter- and intra-fraction fiducial and patient position reproducibility in order to determine appropriate safety margins for liver SBRT treatment on Ethos.

### Study design

A prospective, single arm cohort study.

### Study burden and risks

Nine Hypersight CBCTs will be made of each patient. These will be made over three sessions, with three CBCTs per session (41 mSv or 0.041Gy in total, compared to 48-60Gy of total treatment). The patients will be asked to make these scans in end-exhalation breath-hold, with each breath-hold lasting six seconds. The imaging sessions will last fifteen minutes, and will take place immediately before or after the standard treatment fraction on the Cyberknife. There will be no direct personal benefit for the participants.

## Contacts

**Public**
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL
**Scientific**
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

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

### Inclusion criteria

• Written informed consent;
• Patients discussed in multidisciplinary tumor board;
• Patients diagnosed with liver metastases and referred to the dept. of

Radiotherapy to undergo treatment with stereotactic radiotherapy; or patient >=65 years, diagnosed with HCC and referred to the dept. of Radiotherapy to undergo standard treatment;
• Able to comply with breath-hold requirements.

### Exclusion criteria

• Eligible for surgery, ablation or liver transplantation.

## Study design

### Design

**Study type:** Observational invasive

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-10-2024 |
| Enrollment: | 10 |
| Type: | Anticipated |

### Medical products/devices used

| | |
|---|---|
| Registration: | No |

## Ethics review

Approved WMO

| | |
|---|---|
| Date: | 23-10-2024 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

# 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 | NL86070.078.24 |