# Immediate versus delayed stereotactic ablative radiotherapy (SABR) for patients with pulmonary oligometastases from colorectal cancer: SABR SCAN Trial. A randomised clinical trial

Published: 24-08-2015
Last updated: 19-04-2024

To determine the effect upon progression free survival and upon tumourload relative to baseline, both at one year after randomisation of immediate SABR versus delayed SABR (a scan-and-personalise policy). Secondarily, patterns of progression,...

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Metastases |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON45023

**Source**
ToetsingOnline

**Brief title**
Immediate vs delayed SABR for pulmonary oligometastases

### Condition

- Metastases

**Synonym**
metastases; spread out cancer

**Research involving**
Human

## Sponsors and support

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

## Intervention

**Keyword:** Metastatic tumours, Oligometastases, Stereotactic ablative radiotherapy

## Outcome measures

### Primary outcome

Primary: Rate of progression free survival at one year; tumourload at one year

(relative to baseline).

### Secondary outcome

- Relative change of tumourload at one year after randomisation expressed as

volume of all tumour at one year divided by volume of all tumour at time of

randomisation;

- Time to failure of local strategy (TFLS): failure = death or progressive

disease NOT amenable to local treatment;

- Progression of target lesions and progression outside of target lesions at

one year;

- Health-related quality of life (EURO QOL5), pulmonary symptoms

(EORTC-QLQ-LC13), and emotional distress (Hospital Anxiety and Depression

Scale, HADS).

# Study description

### Background summary

SABR (Stereotactic ablative radiotherapy) is one of the standard treatment

options besides surgical resection for limited lung metastases (oligometastases) from colorectal cancer. High efficacy in terms of local control of metastatic lesions treated has been shown. Nevertheless, the precise effect of SABR upon progression-free- and overall survival in these patients is unknown. To further evaluate and develop local treatment options in metastatic disease, more information is necessary regarding the impact upon * and the pattern of * disease progression of local treatment options such as SABR.

## Study objective

To determine the effect upon progression free survival and upon tumourload relative to baseline, both at one year after randomisation of immediate SABR versus delayed SABR (a scan-and-personalise policy). Secondarily, patterns of progression, patient-reported symptoms and quality of life will be monitored.

## Study design

Randomised phase II clinical study.

## Intervention

Randomisation (1:1) between immediate SABR versus delayed SABR (delayed = treatment six months after randomisation or at disease progression, whichever comes first).

## Study burden and risks

SABR besides surgical metastasectomy is considered as treatment option for patients with limited metastases from colorectal cancer that are technically amenable for local treatment. SABR is a safe (no mortality) and little burdensome treatment that is frequently administered to patients with metastases from various solid tumours outside clinical studies. Although high rates of local control have been shown in case series and single-arm studies, there are no studies investigating the optimal role of SABR in the management of the patient with oligometastatic stage disease. There is also no definitive information about comparative effectiveness of SABR versus surgical metastatsectomy.
One of the major open questions is the optimal point in time to administer SABR (early, or rather later).
Patients participating in the present study might theoretically have a 50% chance of benefit from participation in case they are randomised to the delayed-SABR (scan-and-personalise) arm, if they happen to harbour diffusely spreading disease that is not obvious at the time of considering participation, but at 3 or 6 months follow-up. In that case they might be spared unnecessary local treatment such as SABR, if they happen to get randomised into the experimental arm; they will in this case directly be considered for systemic

treatment.
The risk of missing the stage of treatability by deferring treatment in the experimental arm (scan-and-personalise) is estimated to be minimal because of tumour biological facts: one tumour doubling time frequently equals about the interval to the first CT scan (3 months) with the possibility to initiate SABR (or other local treatment) at that time if appropriate. One tumour-volume-doubling is equal to a 25% increase in diameter, i.e., the largest tumour eligible for the study (30mm) will have grown to a still treatable diameter of 38mm.

## Contacts

**Public**
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700RB
NL
**Scientific**
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700RB
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

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

### Inclusion criteria

- Age * 18 years

- WHO-PS 0 * 1.
- Patients with 1 to 3 lung metastases between 8 mm and 3 cm each, from colorectal cancer. Resection has been considered at a multidisciplinary conference but was not recommended or
has been refused by the patient.
- Possibility to define target lesions that fulfil the following criteria:
* No lesion larger than 3 cm;
* Not more than 3 metastases * 8 mm in total (lesions smaller than 8 mm in diameter are NOT
counted and will NOT be irradiated);
- No prior radiotherapy (SABR or other) within about 2 cm from target lesions (i.e., the distance
between prior PTV to actual intended PTV is more than 2 cm AND dose distribution of former radiation permits SABR).
- Primary tumour has been completely removed surgically.
- Metastases outside target organs (e.g. livermetastases or other) are radically treated locally (resection, RFA, MWA, stereotactic radiotherapy, or other). Earlier resected or ablated (SABR, RFA, MWA) metastases to lung, liver, or other organ form no exclusion criterion. Brain metastases should be completely resected or treated with stereotactic radiosurgery. Bone metastases should be resected or treated with high dose radiotherapy (equivalent of > 40 Gy)
and be asymptomatic.
- Patients at reproductive potential must agree to practice an effective contraceptive method. Women of childbearing potential must not be pregnant or lactating.
- Proficiency in the Dutch language so that quality-of-life questionnaires can be completed in Dutch and absence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial.
- Before patient randomisation, informed consent must be given according to ICH/EU GCP (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH); EU: European Union; GCP: Good clinical practice), and national/local regulations.

## Exclusion criteria

- Any clinical symptoms possibly or certainly caused by index lungmetastases
- Physical inability to undergo stereotactic radiotherapy (e.g., serious shoulder stiffness)
- Any uncontrolled malignancy other than index colorectal cancer
- Other malignancy within recent two years, even if completely under control (under control = no evidence of disease)
- Failure to comply with any of the inclusion criteria.

# 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: | Recruitment stopped |
| Start date (anticipated): | 17-12-2015 |
| Enrollment: | 25 |
| Type: | Actual |

# Ethics review

| | |
|---|---|
| Approved WMO Date: | 24-08-2015 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |
| Approved WMO Date: | 22-02-2017 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

# 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 | NCT02414334 |
| CCMO | NL53079.042.15 |