Stereotactic Ablative Radiotherapy for Comprehensive Treatment of Oligometastatic Tumors (SABR-COMET): A Randomized Phase II Trial

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To assess the impact of a comprehensive oligometastatic SABR treatment program on overall survival and quality of life in patients with up to 5 metastatic cancer lesions, compared to patients who receive standard of care treatment alone.

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

Summary

ID

NL-OMON37922

Source
ToetsingOnline

Brief title
SABR-COMET

Condition

- Metastases

Synonym
cancer spread to other parts of the body, metastatic cancer

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cancer, Oligometastases, Stereotactic Ablative Radiotherapy

Outcome measures

Primary outcome

* Overall Survival, defined as time from randomization to death from any cause.

Secondary outcome

* Quality of life, assessed with the Functional Assessment of Cancer

Therapy: General (FACT-G).

* Toxicity, assessed by the National Cancer Institute Common Toxicity Criteria

(NCI- CTC) version 4 for each organ treated .

* Progression-free survival: time from randomization to disease progression at

any site or death.

* Lesional control rate.

* Number of cycles of further chemotherapy/systemic therapy.

Study description

Background summary

The oligometastatic disease state was first defined in 1995 and refers to an stage of disease where cancer has spread beyond the site of origin, but is not yet widely metastatic. In such a state of limited metastatic disease burden, it is hypothesized that eradication of all sites of metastatic disease could result in long-term survival, or even cure, in some patients. Ablation of metastatic deposits can be achieved surgically, or through stereotactic ablative radiotherapy (SABR), a new radiotherapy technology that delivers very large, hypofractionated doses of radiotherapy to small tumor targets, with high rates of local control.

Study objective

To assess the impact of a comprehensive oligometastatic SABR treatment program on overall survival and quality of life in patients with up to 5 metastatic cancer lesions, compared to patients who receive standard of care treatment alone.

Study design

This study is designed as a randomized phase II screening study. Patients will be randomized between current standard of care treatment (Arm 1) vs. standard of care treatment + SABR (Arm 2) to sites of known disease. Patients will be randomized in a 1:2 ratio to Arm 1 vs. Arm 2, respectively.

Intervention

Patients in the SABR-arm will receive stereotactic ablative radiotherapy to all sites of metastatic cancer. Patients is the other group will receive standard palliative care.

Study burden and risks

All patients will be asked to fill in a questionnaire regarding their quality of life when visiting the hospital for the follow-up visits. This will take about 5-10 minutes per visit.
The patients in the SABR-arm can experience toxicity regarding to the radiation therapy.

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 or older.
Willing to provide informed consent.
Histologically confirmed malignancy with metastatic disease detected on imaging. Biopsy of metastasis is preferred, but not required.
ECOG performance status 0-1.
Controlled primary tumor, defined as: at least 3 months since original tumor treated definitively, with no progression at primary site.
All sites of disease can be safely treated based on criteria below
• Maximum 3 metastases in any single organ system (i.e. lung, liver, brain, bone)
• Life expectancy >6 months
• Not a candidate for surgical resection at all sites: surgery to all sites not recommended by multidisciplinary team, or unfit or declining surgery
• Prior chemotherapy allowed but no chemotherapy (cytotoxic or molecularly targeted agents) therapy 4 weeks prior to first fraction of radiotherapy, during radiotherapy, or for two weeks after last fraction. Hormonal therapy is allowed.
Patients with metastases that have been previously treated (e.g. prior resection, RFA or radiotherapy):
*If that previously treated metastasis is controlled on imaging, the patient is eligible for this study and that site does not need treatment
*If that previously treated metastasis is NOT controlled on imaging:
* If the previous treatment was surgery, the patient is eligible if
that site can be treated by SABR
* If the previous treatment was radiotherapy or RFA, the patient is ineligable;Patient presented at multidisciplinary tumor board or quality-assurance rounds.

Exclusion criteria

Serious medical comorbidities precluding radiotherapy
Bone metastasis in a femoral bone
Patients with 1-3 brain metastasis and no disease elsewhere (these patients should not be randomized but treated with stereotactic radiotherapy as per results of randomized trials)
Prior radiotherapy to a site requiring treatment
Complete response to first-line chemotherapy (i.e. no measurable target for SABR)
Malignant pleural effusion
Inability to treat all sites of active disease
Clinical or radiologic evidence of spinal cord compression OR tumor within 3 mm of spinal cord on MRI.
Dominant brain metastasis requiring surgical decompression
Pregnant or lactating women

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):	12-08-2012
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	24-07-2012
Application type:	First submission

Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-09-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NCT01446744
CCMO	NL40261.029.12