Stereotactic ablative radiotherapy (SABR) after systemic antineoplastic treatment for patients with unresectable oligometastases (lung; liver; adrenal glands) from solid tumours: SARASTRO Trial (Stereotactic Ablative Radiotherapy After Systemic TReatment for Oligometastases) A randomised phase II trial

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To explore, whether the magnitude of the effect - in terms of progression free survival at one year - due to the addition of SABR after chemotherapy for selected patients with metastatic disease from solid (non-germinoma) tumours might justify a...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Metastases
Study type	Interventional

Summary

ID

NL-OMON37714

Source
ToetsingOnline

Brief title
SABR after systemic treatment for 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 (SABR)

Outcome measures

Primary outcome

Primary: Rate of progression free survival at one year.

Secondary outcome

Secondary: Local progression free survival; location of progression: irradiated target lesion / non-irradiated target lesion / both; rate of progression outside target lesions; time to failure of local strategy; relative change of tumour load at one year; rate of metastases in organs primarily unaffected; health-related quality of life and patient-rated specific symptoms; overall survival; same as primary and secondary endpoints assessed at two, three, and five years.

Study description

Background summary

In case systemic antineoplastic therapy is indicated in the metastatic setting of solid tumour treatment, it improves outcome in terms of deferring progression of disease and prolonging survival by reducing tumour load. Systemic antineoplastic treatment can eradicate microscopic tumour, made evident by the increase of the rate of patients cured by adjuvant chemotherapy. However, the induction of complete and permanent remission of macroscopic metastatic tumour deposits is a rare event after systemic therapy. Surgical metastasectomy is considered to be the only curative chance for patients with resectable metastases. Stereotactic ablative radiotherapy (SABR) can induce permanent local sterilisation of macroscopic tumour deposits, often expressed as local control. It is challenging to hypothesize that the combination of systemic drug therapy with locally ablative treatment could improve the outcome for patients with metastatic disease.

Study objective

To explore, whether the magnitude of the effect - in terms of progression free survival at one year - due to the addition of SABR after chemotherapy for selected patients with metastatic disease from solid (non-germinoma) tumours might justify a randomised phase III trial powered for difference.

Study design

Randomised phase II study in order to control for inevitable selection bias due to inclusion criteria.

Intervention

Randomisation (1:1) between SABR to remaining metastases after chemotherapy versus observation.

Study burden and risks

Chemotherapy is regarded standard treatment for most patients with unresectable metastases from solid tumours. SABR is a safe (zero mortality) and little burdensome treatment presently administered to patients with unresectable metastases from various solid tumours outside clinical studies, if chemotherapy is not indicated. Dose limits to critical structures are derived from phase I/II research and single institution series and are implemented to avoid relevant risk due to SABR. Frequently, SABR is presently chosen in order to defer chemotherapy, if patients are to be spared toxicity from systemic chemotherapy even in the absence of evidence from comparative trials. Patients participating might benefit from SABR in case the progression rate is reduced indeed by adding SABR to systemic 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

- Patients above age 18.
- WHO-PS (performance status) 0 - 1.
- Patients with unresectable metastases to lung, and/or liver, and/or one adrenal gland, who have received systemic therapy and show partial remission or stable disease.
- Using RECIST 1.1 criteria (see the Appendix): Partial response or stable disease at restaging (compared with staging prior to last 4*6 cycles of chemotherapy). Note this exception: After bevacizumab-containing treatment, response of liver metastases should be assessed using CT-morphologic criteria as described by Chun et al., JAMA 2009;302:2338
- Possibility to define target lesions that fulfil the following criteria:
- No lesion larger than 4 cm;
- Not more than 5 metastases >= 8 mm in total (lesions smaller than 8 mm in diameter are NOT counted and will NOT be irradiated);

- Not more than 3 lesions >= 8 mm in the lung;
- Not more than 3 lesions >= 8 mm in the liver;
- If adrenal gland metastasis: only unilateral lesion;
- primary tumour has been completely removed

Exclusion criteria

Not fulfilling the inclusion criteria

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO

Date:	26-03-2012
Application type:	First submission
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
CCMO	NL39005.042.11