Observational cohort of patients treated with stereotactic radiotherapy for Oligo LYMPh nOde and other soft tissue metastasiS; the OLYMPOS cohort

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29672

Source
Nationaal Trial Register

Brief title
OLYMPOS

Health condition

oligometastatic cancer

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: This work was supported by the Dutch Cancer Society under Grant 2015-0848.

Intervention

Outcome measures

Primary outcome

progression free survival after SBRT

Secondary outcome

Physician-reported toxicity (CTCAE), overall survival, time until start of systemic treatment, patient-reported Quality of Life

Study description

Background summary

Rationale: With improved volumetric imaging modalities, oncological patients are increasingly diagnosed with limited soft tissue (oligo)metastatic disease (i.e. nodal, adrenal, liver, muscle or other soft tissue lesions) after having been treated for primary tumors. These patients are regularly treated with stereotactic radiotherapy to the detected lesions, aiming for local control and for postponement of systemic treatments (chemotherapy, immunotherapy or hormonal treatment) from which patients may benefit more in case of more extended metastatic disease. However, our knowledge concerning selection criteria for stereotactic radiotherapy in this patient group is limited. We have only limited data on the radiation dose and the fractionation schedule that are needed and on treatment outcome in terms of target response and morbidity. Additionally, new (radiotherapy) interventions are becoming available from which patients with oligometastatic disease might profit.

Objectives:
1. To prospectively collect data on patients being treated with stereotactic radiotherapy for soft tissue oligometastases at UMCU
2. To establish criteria for better defining which patients with oligometastatic soft tissue disease might benefit most from stereotactic radiotherapy.
3. To create an infrastructure for efficient, fast and pragmatic evaluation and implementation of new (radiotherapy) interventions.

Study design: Observational, prospective cohort study, according to the ‘cohort multiple Randomized Controlled Trial’ (cmRCT) design.

Study population: All patients with lymph node, adrenal, liver, muscle or other soft tissue oligometastases referred to the Department of Radiation Oncology (UMCU).

Main study parameters and endpoints: Clinical parameters (oncological history, symptoms, imaging, technical and treatment data), radiotherapy parameters (dose, fractionation, treatment margins), clinical endpoints (toxicity, time to progression, time to start systemic treatment, survival) and patient reported outcomes (QoL).

Study objective

The main clinical challenge remains to identify patients who may benefit from aggressive local treatment (stereotactic radiotherapy, SBRT) of soft tissue oligometastases: for which patients can systemic treatment be postponed? Patients who are diagnosed with additional metastases in <6 months after the radiotherapy treatment, could have been spared the radiotherapy treatment: achieving local control has little clinical relevance in the palliative setting that follows. Patients who experience complaints from soft tissue metastases, such as pain or neurological symptoms, may be treated with a true palliative intention with more appropriate radiotherapy treatment schedules. We aim at better prediction of progression free survival, in order to allow improved patient selection for SBRT treatment of oligometastatic disease.
One of the lacunas in knowledge about treatments for oligometastatic disease is the optimal radiotherapy treatment schedule for SBRT. Currently, in our department we treat patients with lymph node oligometastases with 5 fractions of 7 gray (Gy), but various treatment schedules have been reported in literature. The administration of radiation dose on the target volume is very precise in SBRT, but the dose received by surrounding healthy organs may show important variations between the different treatment sessions. Currently this limits us in choices regarding the radiotherapy treatment schedule; it has been advocated that a higher biological effective dose may be needed for achieving optimal long-term local control. With better knowledge of the radiation dose that will be received by surrounding healthy organs, and improved sparing of these organs at risk (OAR), we hypothesize that it may be possible to safely increase the radiation dose per fraction (dose escalation). Furthermore, it may be possible to decrease the number of treatment sessions (hypofractionation). Investigating the potential for dose escalation and hypofractionation in nodal SBRT are goals for future studies that we want to facilitate in the OLYMPOS cohort.

Study design

Oncological outcomes such as progression-free survival, overall survival and time until start of systemic treatment will be investigated up to 5 years after the (first) OLYMPOS SBRT treatment.
Physician-reported toxicity will be reported at the time points for which it is available, generally this is once during treatment (treatment is usually spread over 1-2 weeks), once after 1 week, once after 4 weeks and once after 3 months. Most patients will then be referred back to the referring physician, so we mainly look at acute toxicity after SBRT, but grade >= 3 toxicity is also investigated using a biannual SAE questionnaires.
Patients will be asked to fill in quality of life questionnaires before the start of treatment, and after 1 and 4 weeks, 3 and 6 months after radiotherapy, and then every 6 months until 5 years after radiotherapy or until a next oncological treatment other than radiotherapy is initiated.

Intervention

stereotactic radiotherapy (SBRT) of soft tissue oligometastases

Contacts

Public
UMC Utrecht department of Radiotherapy
Anita Werensteijn-Honingh

+31887569277
Scientific
UMC Utrecht department of Radiotherapy
Anita Werensteijn-Honingh

+31887569277

Eligibility criteria

Inclusion criteria

Patients are eligible when they meet the following criteria:
• Is referred for, or will receive, stereotactic radiotherapy of a soft tissue metastasis with a localization other than brain or lung.
• Informed consent – at least – for use of routinely collected clinical data for research purposes (including follow up data in other hospitals)

Exclusion criteria

Patients are ineligible when they meet the following criteria:
• Age <18 years
• Mentally incompetent patients

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-12-2017
Enrollment:	700
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	01-02-2021
Application type:	First submission

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
NTR-new	NL9252
Other	METC Utrecht : METC 17-822 (and 17-411, which was the non-WMO predecessor of the current OLYMPOS study)

Study results

Summary results
https://doi.org/10.1080/0284186X.2021.1955970