Adaptive Fractionation in Online-Adaptive Stereotactic Radiotherapy for Abdominopelvic Lymph Node Oligometastases

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Primary: Can the number of online adaptive fractions be reduced by 30%?Secondary: What is the overall survival, local control, and toxicity? What is the movement of the bowel during treatment? Is there added value in re-aligning the patient when...

Ethical review	Approved WMO
Status	Pending
Health condition type	Metastases
Study type	Interventional

Summary

ID

NL-OMON57107

Source
ToetsingOnline

Brief title
STEAL-3

Condition

- Metastases

Synonym
local lymph node metastases, Lymph node oligometastases

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W,Investigator initiated grant - Varian Medical Systems,Varian Medical Systems

Intervention

Keyword: Adaptive Radiotherapy, Fraction reduction, Lymph nodes, Oligometastases

Outcome measures

Primary outcome

Reduction of the average number of fractions by 30%, by using online adaptive stereotactic radiotherapy for patients with lymph node oligometastases in the abdomen or pelvis.

Secondary outcome

Total survival duration, local control, toxicity, bowel movement during treatment via CBCT scans, and the impact of realigning the patient if excessive movement occurs during treatment.

Study description

Background summary

Oligometastases, a state of cancer with up to five metastases, was traditionally treated with systemic treatments like chemotherapy. Stereotactic body radiotherapy (SBRT) did show a high local control and improved disease-free survival.

The use of SBRT also allows for the deferral of systemic treatment, thereby delaying its potential side effects. SBRT enables the delivery of a high dose to the tumor while minimizing the dose to organs at risk, reducing normal tissue damage. However, toxicity remains a potential issue in the abdominopelvic region, where lymph node oligometastases are often located near, highly mobile, radiosensitive organs like the bowel.

Online adaptive radiotherapy is used to address this issue, adapting the treatment plan to the anatomy of the day. However, adaptive radiotherapy results in longer treatment delivery times than conventional radiotherapy. This

can potentially be countered by increasing the fraction dose and reducing the number of fractions if the patient anatomy allows it. This is convenient for the patient as it reduces the number of hospital visits, and it could also reduce the total workload for the hospital. Therefore, there is not only a benefit of a reduction in toxicity by adaptive treatment, but also in reducing the total treatment time. This study aims to investigate if the number of adaptive fractions can be reduced by 30% for our study population.

Study objective

Primary: Can the number of online adaptive fractions be reduced by 30%?

Secondary: What is the overall survival, local control, and toxicity? What is the movement of the bowel during treatment? Is there added value in re-aligning the patient when there has been excessive movement?

Study design

Phase II, single arm, non randomised clinical trial.

Intervention

The treatment will consist of online-adaptive SBRT using the ETHOS linear accelerator. The standard treatment will be 45Gy/5Fx. If the patient anatomy allows, the number of planned fractions will be isotoxically reduced, keeping OAR and target dose goals biologically equivalent, to a minimum of 25Gy/1Fx. For the adaptive treatment, daily HyperSight CBCT scans will be made, and the target and OAR contours will be automatically delineated and adjusted if necessary. If, during treatment, patient anatomy changes in such a way that fewer or more fractions are required than planned, changes can be made in the daily dose and number of remaining fractions. During and after treatment a CBCT scan is also made to verify current and improve future treatments.

Study burden and risks

Patients may experience early symptoms such as pain, nausea, vomiting, diarrhea, and bleeding, as well as late toxicity symptoms like chronic pain, diarrhea, stenosis, and fistulas. The treatment is delivered in 1 to 5 fractions. For all patients, the risk of toxicity will be significantly reduced by the implementation of adaptive treatment, due to the re-optimization of plans based on the patient anatomy. The treatment with the reduced number of fractions, while conventionally posing a higher risk of side effects, reduces the treatment burden as patients need to visit the hospital only once. It should be noted that the constraints for the organs at risk are isotoxic and are always prioritised over the target.

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 with abdominal and/or pelvic lymph node recurrences of solid tumors.

No more than 5 metastatic lesions in no more than 2 organs and a controlled primary tumor site.

Diagnostic imaging includes at least a PET scan or CT thorax/abdomen, of which one is not older than 4 weeks at the time of referral for SBRT.

Primary tumor must be treated at least 4 months before the diagnosis of metastasis.

Patients must be 18 years or older.

Written informed consent

Exclusion criteria

Prior radiotherapy in the same field.

Second primary malignancy except in situ carcinoma of the cervix, adequately treated non-melanoma skin cancer, or other malignancy treated at least 3 years.

Serious concomitant systemic disorders that would compromise the safety of the patient or his/her ability to complete the study, at the discretion of the investigator.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2024
Enrollment:	25
Type:	Anticipated

Ethics review

Approved WMO

Date:	18-11-2024
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	NL87228.078.24