Online Adaptive stereotactic radiotherapy for abdominopelvic lymphnode oligometastasis.

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To determine local control of SBRT treatment for abdominopelvic oligometastasis based on a fractionation scheme of 45 Gy in 5 fractions, to evaluate local control, survival and toxicity. Use of the plan of the day as a tool for optimize tumor...

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

Summary

ID

NL-OMON45533

Source
ToetsingOnline

Brief title
STEAL

Condition

- Metastases

Synonym
abdominopelvic lymphnode oligometastasis

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

Intervention

Keyword: abdomen, adaptive, oligometastasis, stereotactic

Outcome measures

Primary outcome

Determine local control of Stereotactic radiotherapy treatment in patients with

abdominal and pelvic lymph node oligometastases.

Secondary outcome

Determine overall survival

Toxicity of treatment (NCI CTCAE).

Study description

Background summary

Oligometastasis is decribed as an an intermediate state of cancer spread between localized disease and widespread metastases. They may arise from distinct type of primaries such as (sarcoma, breast cancer, colorectal cancer, etc,) and if lymph node involvement is not associated with an important concomitant metastatic spread, it is reasonable to offer a chance of cure with radical intent.
Metastases in lymph node(s) after primary treatment is considered a sign of disease dissemination and as such is rarely approached with local treatment like surgery or limited-field radiotherapy. Systemic therapy like chemotherapy, endocrine treatment or new biological agents are considered the golden standard in patients with lymph node recurrent cancer. Online-adaptive SBRT is a modality therapy that utilizes stereotactic principles for dose localization and delivers multiple beams to well defined targets in a few fractions. As a result, this technique can deliver higher doses to tumors due to reduced mechanical error margins, and thus cause less normal tissue damage.
A Ct scan will be made before the start of each fraction with online-adaptive SBRT, and the treatment can be adapted by treating with another treatment plan. Before the start of treatment, 2 or 3 other treatment plans (B, C, D) will be made. At the moment of treatment, a treatment plan B, C, or D can be chosen if the treatment plan gives more dose to the tumor and/or the organs at risk

receive less dose. If there is no gain with treatment plan B, C of D then the standard plan A will be used for the treatment.

Study objective

To determine local control of SBRT treatment for abdominopelvic oligometastasis based on a fractionation scheme of 45 Gy in 5 fractions, to evaluate local control, survival and toxicity. Use of the plan of the day as a tool for optimize tumor coverage and minimize toxicity.

Study design

Non-randomized single arm of a prospective phase II study of SBRT for abdominopelvic lymph node metastases.

Intervention

Before every fraction of the radiotherapy, a CT scan will be made.

Study burden and risks

The current evidence for Stereotactic Radiotherapy for treatment abdominopelvic lymphnode oligometastases is based on small retrospective and prospective data. It is a feasible treatment, with local control rates at 2 years ranging from 64-77%.
With SBRT, the gastrointestinal tract is one of the most important dose-limiting organs. Bowel toxicity might present with acute symptoms as pain, nausea, vomiting, diarrhea and bleeding, as well as late toxicity symptoms include chronic pain, diarrhea, stenosis and development of fistulas. Grade 3 toxicity ranged from 3% up to 22%.
Two benefits are expected from the study: The first is a high local control due to the on-line adaptive radiotherapy. An in-room Cone Beam CT (CBCT) scan acquired just before dose delivery is used to select the treatment plan that fits to the best observed anatomy in order to improve local control by creating a better dose coverage of the PTV. The second benefit is to minimize toxicity by reducing the dose in the organs at risk with the use of the plan of the day.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Groene Hilledijk 301
Rotterdam 3075 EA

NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Groene Hilledijk 301
Rotterdam 3075 EA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Indication to SBRT after discussion in Institutional Tumor Board
* Patients with abdominal and/or pelvic lymph node metastases 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 and 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 the metastasis
* Patients must be 18 years or older

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 previously without evidence of recurrence.
* Pregnancy.
* 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 type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2017
Enrollment:	53
Type:	Anticipated

Ethics review

Approved WMO

Date:	12-07-2017
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	NL58442.078.17