A radical Chemoradiation schedule with hypofractionated radiotherapy plus capecitabine for esophageal cancer patients that are unfit for the standard chemoradiation; a phase II study

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a combination of 16 x 3.125 Gy plus twice daily capecitabine (825 mg\m2) is feasible for patients considered unfit for the standard radiochemotherapy (50,4 Gy + carboplatin and paclitaxel)

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25277

Source
Nationaal Trial Register

Brief title
Cradle study

Health condition

non-metastasized esophageal cancer

Sponsors and support

Primary sponsor: amsterdamumc
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

compliance to treatment

Secondary outcome

locoregional control

Study description

Background summary

Rationale: This prospective study investigates the feasibility and toxicity of a hypo-fractionated radiation regime combined with an oral sensitizing drug (Capecitabine) in patients with a locally advanced esophageal tumor who are considered unfit for the standard chemoradiotherapy. Introduction: Technically irresectable or medically inoperable patients in a curable stage of disease of esophageal cancer are referred for curatively intended chemoradiation. The standard chemoradiation schedule consists of 50,4 Gy with 6x weekly Carboplatin and Paclitaxel. This schedule has a curative intent (3-years OS = 40%) but leads to grade III toxicity in about one third of the patients, with an excess in toxicity in older patients. This standard CRT regime is often considered too heavy for old or unfit patients. For patients considered not eligible for the standard chemoradiation, a palliative radiotherapy only schedule remains. The Dutch national radiation guideline suggests for unfit patients a hypo fractionated scheme of 50 Gy in 16 fractions, which is considered feasible in this patient group. However, radiation only for esophageal cancer should be considered as palliative. The combination of radiation with sensitizing chemotherapy has proven to change the intend from palliative to curative. Capecitabine, an oral drug which metabolizes in the body to the active drug 5-FU, is a well-known radiosensitizer, with a mild toxicity profile, which can be adapted quickly and easy according to the encountered toxicity. Primary question is whether this mild sensitizing drug combined with a high dose hypofractionated radiation regime to the esophageal region is feasible in this unfit patient group. Second question is whether this new schedule might lead to long term loco regional tumor control en thus eventually cure. Feasibility will be assessed as the number of patient completing the course. If feasible, and considered less toxic than the standard chemoradiaton regime, a national comparative study will be conducted between radiation with and without capecitabine. Objective: To investigate feasibility of a hypofractionated radiation schedule combined with daily Capecitabine for esophageal cancer patients considered unfit for standard chemoradiation Study design: A phase II prospective interventional drug study

Study objective

a combination of 16 x 3.125 Gy plus twice daily capecitabine (825 mg\m2) is feasible for patients considered unfit for the standard radiochemotherapy (50,4 Gy + carboplatin and paclitaxel)

Study design

none

Intervention

adding capecitabine to the standard radiation schedule

Contacts

Public
amsterdamumc
maarten hulshof

020-4444110
Scientific
amsterdamumc
maarten hulshof

020-4444110

Eligibility criteria

Inclusion criteria

- Age of 18 years or older - WHO performance score 0-3 - Biopsy proven carcinoma of the esophagus - cT1-T4aN0-3M0, including patients with M1 disease based on pathologic nodes at supraclavicular or truncus coeliacus level - The multidisciplinary team rejects surgical treatment - The radiation oncologist and medical oncologist consider patient not eligible for the standard chemoradiation, with at least one of the following characteristics: WHO performance 3, age of > 80 year, metabolic disorders excluding Carboplatin or Paclitaxel, mainly wheelchair bounded, evidence of interstitial lung disease or active, non-infectious pneumonitis, or a Charlson index of 3 or more.

Exclusion criteria

- Previous irradiation overlapping with the intended fields - Stent in situ - Serum DPD deficiency - Prior intravenous chemotherapy for esophageal cancer - An active infection requiring systemic therapy - Has known psychiatric disorders or substance abuse disorders that would interfere with cooperation in the trial - Inability, or serious suspicion of inability to administer the prescribed doses of capecitabine - Is pregnant or breast feeding

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-03-2021
Enrollment:	28
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

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

Study registrations

Followed up by the following (possibly more current) registration

ID: 57178
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9246
Other	METC AmsterdamUMC : METC 2020.0721
CCMO	NL75846.029.21
OMON	NL-OMON57178

Study results

Summary results
NL75846.029.20 Eudract2020-006164-85