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)

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25277

Bron
NTR

Verkorte titel
Cradle study

Aandoening

non-metastasized esophageal cancer

Ondersteuning

Primaire sponsor: amsterdamumc
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

compliance to treatment

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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)

Onderzoeksopzet

none

Onderzoeksproduct en/of interventie

adding capecitabine to the standard radiation schedule

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	15-03-2021
Aantal proefpersonen:	28
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	02-02-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 57178
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
NL75846.029.20 Eudract2020-006164-85