Neoadjuvante chemoradiotherapie gevolgd door chirurgie versus actieve surveillance bij patiënten met een oesofaguscarcinoom

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Active surveillance is non-inferior to surgery in patients with oesophageal cancer showing complete clinical response after neoadjuvant chemoradiotherapy.

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	Maagdarmstelsel therapeutische verrichtingen
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25016

Bron
NTR

Verkorte titel
SANO

Aandoening

- Maagdarmstelsel therapeutische verrichtingen

Aandoening

Oesophageal cancer, oesofaguscarcinoom, esophageal cancer, active surveillance

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Erasmus MC

Overige ondersteuning: Ministry of Health, Welfare and Sport (ZonMW)
Koningin Wilhelmina Fonds (KWF) Kankerbestrijding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Overal survivall

Toelichting onderzoek

Achtergrond van het onderzoek

We propose an active surveillance approach after completion of neoadjuvant chemoradiotherapy (nCRT) for carcinoma of the oesophagus. In this SANO (i.e. Surgery As Needed for Oesophageal cancer) approach, surgical resection is offered only to patients in whom a locoregional regrowth is highly suspected or proven, without distant dissemination. Such an organ-preserving strategy can have great advantages, but is only justified if long-term survival is non-inferior to that of the current standard trimodality approach comprising neoadjuvant chemoradiotherapy followed by standard surgery. The aim of this study is to assess the (cost-)effectiveness (including non-financial costs and survival) of active surveillance for patients with squamous cell- or adenocarcinoma of the oesophagus or oesophago-gastric junction.

Doel van het onderzoek

Active surveillance is non-inferior to surgery in patients with oesophageal cancer showing complete clinical response after neoadjuvant chemoradiotherapy.

Onderzoeksopzet

See interventions

Onderzoeksproduct en/of interventie

Approximately 4-6 weeks after completion of nCRT all patients will undergo a first clinical response evaluation (CRE-I) consisting of endoscopy with (random) bite-on-bite biopsies of the primary tumour site and of any other suspected laesions in the oesophagus. Patients who are clinically complete responders (i.e. patients without local or disseminated disease proven by histology) will undergo a second clinical response evaluation (CRE-II), 6-8 weeks after CRE-I (i.e. 10-14 weeks after completion of nCRT). CRE-II will include a whole body 18F-FDG PET-

CT, followed by endoscopy with (random) bite-on-bite biopsies of the primary tumour site and any other suspected laesions in the oesophagus, radial EUS for measurement of tumour thickness and ¨Carea and linear EUS plus FNA of suspected lymph nodes. Patients who have a clinically complete response after CRE-II will be assigned to either surgical resection or active surveillance. During the first phase of the study, these patients will undergo surgical resection, which is standard practice. After this phase, centres will change their policy to active surveillance, with the duration of the first phase determined randomly over the 12 centres (i.e. stepped wedge cluster design). Patients enrolled in the active surveillance arm will undergo diagnostic evaluations similar to CRE-II every 3 months in the first year after completion of neoadjuvant treatment, every 4 months in the second year, every 6 months in the third year and yearly in the 4th and 5th year of follow up, or when symptoms or results of any diagnostic test require shorter assessment intervals. In the active surveillance arm, surgical resection will be offered only to those patients, in whom a locoregional regrowth is highly suspected or proven, without any signs of distant dissemination.

Contactpersonen

Publiek

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Deelname eisen

Leeftijd

Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)
65 jaar en ouder
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patients who are planned to undergo neoadjuvant chemoradiotherapy according to CROSS, followed by surgical resection for histologically proven oesophageal squamous cell carcinoma or adenocarcinoma of the oesophagus or oesophago-gastric junction, without distant dissemination;

- Age ≥18;

- Written, voluntary, informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Language difficulty, dementia or altered mental status prohibiting the understanding and giving of informed consent and to complete quality of life questionnaires;

- Non-FDG-avid tumour at baseline PET-CT scan.

Onderzoeksopzet

Opzet

Fase onderzoek:	N.V.T.
Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-11-2017
Aantal proefpersonen:	300
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6626
NTR-old	NTR6803
Ander register	Erasmus MC : EMC17-392-SANO

Resultaten