Surgery As Needed for Oesophageal cancer -2

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Active surveillance is safe in patients with oesophageal cancer and a clinically complete response after neoadjuvant chemoradiotherapy outside the SANO trial.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26542

Bron
Nationaal Trial Register

Verkorte titel
SANO-2

Aandoening

Oesophageal cancer, oesofaguscarcinoom, esophageal cancer, active surveillance

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: Erasmus MC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study endpoint is the number of patients with adverse events registered in the SANO-2 study (safety).

Toelichting onderzoek

Achtergrond van het onderzoek

An active surveillance approach after completion of neoadjuvant chemoradiotherapy for locally advanced oesophageal cancer is being investigated in the SANO (Surgery As Needed for Oesophageal cancer) trial, that completed patient inclusion in December 2020. First long term results are expected end 2023. Based on current retrospective studies and short term results of the SANO, to date there is no evidence that active surveillance is unsafe. Within the follow-up of the SANO trial, the safety of active surveillance is continuously monitored. Based on a high participation rate (>90%) in the SANO trial and on the view of the Dutch patient federation for cancer of the digestive tract (SPKS) to offer active surveillance as an alternative treatment option in a controlled setting, there is a demand for a tailored surgery approach after neoadjuvant chemoradiotherapy until results of the SANO trial are available. When patients request active surveillance outside the SANO trial, it is of the utmost importance to set up a prospective cohort study (extension study) in order to monitor safety, implementation and effectiveness of active surveillance outside the SANO trial before the final results of the SANO trail are available.

Doel van het onderzoek

Active surveillance is safe in patients with oesophageal cancer and a clinically complete response after neoadjuvant chemoradiotherapy outside the SANO trial.

Onderzoeksopzet

See interventions

Onderzoeksproduct en/of interventie

Patients will undergo two clinical response evaluations (CREs) after nCRT (i.e. CRE-1 and CRE-2). During CRE-1 at 5-6 weeks after nCRT patients will undergo oesophagogastroduodenoscopy (OGD) with bite-on-bite biopsies. During CRE-2 at 10-12 weeks after completion of nCRT patients will undergo positron emission tomography with computed tomography (PET-CT), endoscopy with bite-on-bite biopsies and endoscopic ultrasonography (EUS) plus fine-needle aspiration (FNA). If cancer is detected, surgery will be performed. Patients who have cCR are eligible for active surveillance according to the SANO protocol. According to the SANO protocol, these patients are offered decision counselling by an independent doctor who is trained by a medical psychologist for this particular treatment decision. During active surveillance regular CREs are performed to detect regrowth of cancer: 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. Delayed oesophagectomy will be offered to those patients in whom locoregional regrowth is highly suspected or proven, without any signs of distant dissemination.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Operable patients who are planned to undergo or who recently underwent 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
- Age ≥18
- Written, voluntary, informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Non-FDG-avid tumour at baseline PET-CT scan
- Initial treatment with endoscopic resection
- Patients who underwent of who are planned to undergo definitive chemoradiotherapy
- Language difficulty, dementia or altered mental status prohibiting the understanding and giving of informed consent.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	09-03-2021
Aantal proefpersonen:	360
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	09-03-2021
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	NL9322
Ander register	METC Erasmus MC : MEC-2021-0068

Resultaten