

Surgery As Needed for Oesophageal cancer -2

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26542

Source

NTR

Brief title

SANO-2

Health condition

Oesophageal cancer, oesofaguscarcinoom, esophageal cancer, active surveillance

Sponsors and support

Primary sponsor: Erasmus MC

Source(s) of monetary or material Support: Erasmus MC

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Secondary endpoints are the proportion of patients that adhered to the SANO active surveillance protocol (implementation) and effectiveness of active surveillance outside the SANO trial.

Study description

Background summary

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 trial are available.

Study objective

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

Study design

See interventions

Intervention

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.

Contacts

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Scientific

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Eligibility criteria

Inclusion criteria

- 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.

Exclusion criteria

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

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	09-03-2021
Enrollment:	360
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion	
Date:	09-03-2021
Application type:	First submission

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
NTR-new	NL9322
Other	METC Erasmus MC : MEC-2021-0068

Study results