A prospective cohort study on active surveillance after neoadjuvant chemoradiation for oesophageal cancer: SANO-2 study

Published: 08-03-2021
Last updated: 04-04-2024

To monitor safety, implementation and effectiveness of active surveillance before the final results of the SANO trial are available in patients outside a randomized clinical trial.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON52368

Source
ToetsingOnline

Brief title
SANO-2 study

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Endocrine neoplasms malignant and unspecified

Synonym
carcinoma of the oesophagus, oesophageal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Active surveillance, CROSS neoadjuvant chemoradiotherapy, Oesophageal cancer

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 study.

Study objective

To monitor safety, implementation and effectiveness of active surveillance before the final results of the SANO trial are available in patients outside a randomized clinical trial.

Study design

Multicentre prospective observational extension study.

Study burden and risks

The main burden for participating patients are the additional diagnostic tests (CREs) after completion of nCRT. The number and frequency of the set of diagnostics depend on whether residual disease is detected. The CREs consist of PET-CT, endoscopy with bite-on-bite biopsies and endosonography with fine-needle-aspiration of suspected lymph nodes. All three tests carry a minimal risk of complications (0.7% minor complications and no major complications have been reported in >1500 endoscopies). It is still unclear if those who have a cCR and undergo active surveillance beyond 12 weeks have comparable survival or if delayed oesophagectomy is associated with potential risks in case of regrowth of cancer (e.g. irresectable disease, postoperative morbidity, higher distant dissemination rate). Strict stop rules for the SANO trial have been formulated that are continuously monitored. If a stop rule of the ongoing SANO trial is violated, patients registered in the SANO-2 study can be easily identified and can be informed accordingly. Those patients will be offered immediate (high priority) resection, even in the absence of suspicion of regrowth. Participating patients may benefit from personalised timing of surgery, at 6 or 12 weeks, and by the avoidance of unnecessary oesophagectomy, which is associated with severe morbidity, substantial postoperative mortality and permanent impact on patients* quality of life.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL

Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

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 of 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 invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-03-2021
Enrollment:	900
Type:	Actual

Ethics review

Approved WMO Date:	08-03-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-06-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-08-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-02-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-10-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-05-2023

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
ClinicalTrials.gov	NCT04886635
CCMO	NL76567.078.21