# 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**
Nationaal Trial Register

**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 trail 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

**Public**
Erasmus MC
Charlène van der Zijden

010 704 1223
**Scientific**
Erasmus MC
Charlène van der Zijden

010 704 1223

# 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 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 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