# SURVive: investigating new imaging criteria for non-operative treatment following neoadjuvant chemoradiation in rectal cancer patients

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Evaluation of the feasibility of the combination of (DW-)MRI and digital FDG-PET/CT for prediction of response to chemoradiation therapy.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Malignant and unspecified neoplasms gastrointestinal NEC |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON48971

**Source**
ToetsingOnline

**Brief title**
Novel imaging criteria after neoadjuvant therapy rectal cancer.

### Condition

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

**Synonym**
Rectalcancer, rectalcarcinoma

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Heelkunde

**Source(s) of monetary or material Support:** ERC SURVive grant van Professor C.J.H. van de Velde.

## Intervention

**Keyword:** DW-MRI, FDG-PET, Neoadjuvant therapy, Rectalcancer

## Outcome measures

### Primary outcome

Evaluation of the accuracy of the combination of clinical data, MRI and digital

FDG-PET/CT for prediction of response to chemoradiation therapy.

### Secondary outcome

NVT

# Study description

### Background summary

Following the great success of neoadjuvant treatment, recently, studies have addressed the non-operative treatment for rectal cancer patients. Especially in locally advanced rectal cancer, a pathological complete response (pCR) after chemoradiation therapy correlates positively with outcome and it has been suggested that these patients could be managed less invasively or even without surgery. This would be a very important improvement in rectal cancer treatment, as the current surgical treatment can lead to significant short- and long-term complications and functional problems in the majority of patients. Up to 20% of patients have a complete remission of their rectal tumor and lymph nodes after neoadjuvant treatment. Although this could mean that surgery is no longer required and major complications can be avoided, these patients (with a clinical complete response on imaging, cCR) cannot be accurately selected by the currently available imaging modalities.
Both MRI and FDG-PET/CT have their limitations in the prediction of pCR. Diffusion Weighted-MRI (DW-MRI) can provide information related to tumor cellularity and the integrity of cell membranes and is sensitive to intratumoral changes induced by chemotherapy. Digital FDG-PET/CT visualizes changes in glucose metabolism and provides higher time-of-flight resolution images when compared to conventional FDG-PET/CT. The combination of both could possibly have complimentary value to predict pCR in those patients in whom surgery could potentially be avoided. Available data in the literature is

currently insufficient to evaluate such a multimodality imaging approach.

### Study objective

Evaluation of the feasibility of the combination of (DW-)MRI and digital FDG-PET/CT for prediction of response to chemoradiation therapy.

### Study design

As a pilot study, we want to include 20 patients. All patients who meet the inclusion criteria are asked to participate in this study. The combined value of MRI and digital FDG-PET/CT, in the prediction of response to chemoradiation will be evaluated observationally. Results will be compared to the current standard imaging methods. Since this trial is a pilot study, no formal power analysis has been performed.

### Study burden and risks

Patients will receive 3 additional FDG-PET/CT scans and 1 additional (DW-)MRI scan. Three hours will be calculated for the FDG-PET/CT scan and 2 hours for the MRI scan.
Radiation of the FDG-PET/CT is minimal and will not lead to any changes in normal metabolism of the human body.
Only an allergic reaction to the FDG is possible but has only occured in very few cases. In case of a reaction, trained personell is closeby and will handle the situation.

## Contacts

**Public**
Selecteer

Albinusdreef 3
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NL
**Scientific**
Selecteer

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

Patients with rectal cancer who are eligible for treatment with neoadjuvant chemoradiation
Patients treated in the LUMC, HMC, Alrijne or GHZ.
Age 18 years and older;
Willing to participate in all aspects of the study

## Exclusion criteria

Patients with rectal cancer, receiving chemoradiation as part of the TESAR trial
Diabetes mellitus
Claustrofobia (low dose benzodiazepines are allowed);
Prior radiotherapy to the pelvis
If female and fertile: signs and symptoms of pregnancy or a positive pregnancy test / breast-feeding (a formal negative pregnancy test is not obligatory);
Presence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule
Contraindications for Magnetic Resonance Imaging
Patient has evidence of infection in the 14 days prior to the FDG-PET/CT scan localised to the lower abdomen, pelvic region, lower back, inguinal region;
Inability to tolerate lying supine for the duration of an FDG-PET/CT examination (~30min)

# Study design

## Design

**Study type:** Observational invasive

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 10-07-2018 |
| Enrollment: | 20 |
| Type: | Actual |

# Ethics review

Approved WMO

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|---|---|
| Date: | 04-07-2018 |
| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

Approved WMO

| | |
|---|---|
| Date: | 30-08-2018 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

Approved WMO

| | |
|---|---|
| Date: | 15-10-2018 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

Approved WMO

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|---|---|
| Date: | 05-12-2018 |

| | |
|---|---|
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br>metc-ldd@lumc.nl |
| Approved WMO Date: | 29-05-2019 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br>metc-ldd@lumc.nl |
| Approved WMO Date: | 13-01-2020 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br>metc-ldd@lumc.nl |

# 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 |
|---|---|
| CCMO | NL64390.058.17 |