# The value of CTPET scans for the prediction of response after treatment in rectal cancer.

No registrations found.

| | |
|---|---|
| **Ethical review** | Not applicable |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON24449

**Source**
NTR

**Health condition**

Pathologic complete response, prediction, rectal cancer, machine learning, chemoradiotherapy, PET

### Sponsors and support

**Primary sponsor:** Maastro Clinic
Dr.Tanslaan 12
6229 ET Maastricht
**Source(s) of monetary or material Support:** Maastro Clinic
Dr.Tanslaan 12
6229 ET Maastricht

### Intervention

### Outcome measures

**Primary outcome**

Pathologic complete response, defined by ypT0N0 stage extracted from pathologic reports.

### Secondary outcome

1. Local control;

2. Distant metastases;

3. Survival;

4. Relapse free survival;

5. Metastases free survival.

## Study description

### Background summary

Accurate prediction of pathologic complete response can help in the selection of patients for optimized treatment, sphincter-preserving surgery, less extensive resection, planning of extra radiation boosts, or even delayed surgery with a wait-and-see policy. Therefore it is valuable to develop an accurate, data-driven model to predict pathologic complete response for rectal cancer patients in order to individualize treatment. CTPET-imaging is known to have predictive value for response in rectal cancer from univariate analyses. In this study CTPET imaging is combined with clinical prognostic factors to develop models and corresponding nomograms to predict response sufficiently accurate to use in trials and in the clinic.

### Study objective

A model based on the combination of clinical prognostic factors and features extracted from tumor contours from CTPET has a high accuracy to predict pathologic complete response after chemoradiotherapy in locally advanced rectal cancer.

### Study design

N/A

### Intervention

1. FDG-PET imaging (pretreatment);

2. Blood sampling (facultative);

3. FDG-PET imaging (posttreatment, facultative).

# Contacts

**Public**
Dr. Tanslaan 12
Ruud Stiphout, van
Maastricht 6229 ET
The Netherlands
+31 (0)88 4455666
**Scientific**
Dr. Tanslaan 12
Ruud Stiphout, van
Maastricht 6229 ET
The Netherlands
+31 (0)88 4455666

# Eligibility criteria

## Inclusion criteria

1. Histological proven rectal cancer;

2. Only primary tumors; no recurrences;

3. Only concurrent chemoradiotherapy treatment;

4. 18 years or older.

## Exclusion criteria

1. No adenocarcinoma histology;

2. History of prior pelvis radiotherapy.

# Study design

## Design

Study type: Observational non invasive

| | |
|---|---|
| Intervention model: | Parallel |
| Allocation: | Non controlled trial |

**Control:** N/A , unknown

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-01-2004 |
| Enrollment: | 500 |
| Type: | Anticipated |

## Ethics review

Not applicable

| | |
|---|---|
| Application type: | Not applicable |

## 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 | NL2049 |
| NTR-old | NTR2166 |
| Other | : |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Study results

**Summary results**
N/A