Investigating new imaging criteria for non-operative treatment following neoadjuvant chemoradiation in rectal cancer patients

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22673

Source
Nationaal Trial Register

Brief title
SURvive

Health condition

Rectal cancer

Sponsors and support

Primary sponsor: Leiden Unversity Medical Center
Source(s) of monetary or material Support: European Research Council

Intervention

Outcome measures

Primary outcome

SUVmax, ADC

Secondary outcome

TLG, SUVmax change

Study description

Background summary

A single-arm multicentre pilot study to assess the feasibility of combining digital FDG-PET/CT and (DW-)MRI in predicting response to neoadjuvant chemoradiation in patients with locally advanced rectal cancer.

Study objective

Combining digital FDG-PET/CT and DW-MRI imaging will more accurately predict and define response in rectal cancer patients after neoadjuvant treatment.

Study design

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Intervention

Digital FDG-PET/CT, DW-MRI.

Contacts

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Eligibility criteria

Inclusion criteria

Biopsy proven adenocarcinoma of the rectum
Patients with locally advanced rectal cancer who, according to current guidelines, are eligible for treatment with neoadjuvant chemoradiation
Patients treated in the LUMC, HMC, Alrijne Leiderdorp or Groene Hart Ziekenhuis Gouda.
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:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2018
Enrollment:	20
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	03-03-2019
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	NL7563
Other	METC LUMC : METC P18.023

Study results