

Rectal Mucosal Perfusion and Oxygenation in Patients with Rectal Cancer; Variables to Predict Response to Radiation Therapy and Anastomotic Leakage?

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To investigate if there is a correlation between tumor perfusion and oxygenation, and downgrading of the tumor. This in order to better select those patient upfront, who will truly benefit from adjuvant radiation therapy.

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON32076

Source

ToetsingOnline

Brief title

Rectal Mucosal Perfusion and Oxygenation in Patients with Rectal Cancer

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym

rectal cancer, rectal carcinoma

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: stichting digestieve chirurgie

Intervention

Keyword: anastomotic leakage, neoadjuvant therapy, perfusion, rectal cancer

Outcome measures

Primary outcome

-Correlation between perfusion and oxygenation in tumor and rectal mucosa and downgrading of the tumor.

Secondary outcome

-Radiation therapy induced changes in the perfusion and oxygenation of the rectal mucosa.

-Correlation between rectal mucosal perfusion and oxygenation and anastomotic leakage.

Study description

Background summary

Neoadjuvant radiation therapy has become standard in patients with mid and low rectal cancer in order to improve local control and reduce tumor load.

Study objective

To investigate if there is a correlation between tumor perfusion and oxygenation, and downgrading of the tumor. This in order to better select those patient upfront, who will truly benefit from adjuvant radiation therapy.

Study design

Perfusion and oxygenation in the rectal mucosa and central tumor will be measured with the laser-Doppler-spectrophotometry O2C-device before radiation

therapy and just before surgical resection of the tumor (6-8 weeks following radiation therapy). Downgrading of the tumor will be evaluated according to imaging with the MRI and histology reports from the pathology department.

Study burden and risks

At the same time as perfusion measurements blood will be drawn, which would not have been done otherwise. The other perfusion measurements will be carried out during other regular diagnostic procedures and therefore do not form an additional burden for the patient.

Contacts

Public

Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Postbus 7700, 1000 SN Amsterdam
Nederland

Scientific

Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Postbus 7700, 1000 SN Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

1. Patients undergoing neoadjuvant radiation therapy at the VU University medical center for rectal cancer.
2. age 18 years and older
3. informed consent

Exclusion criteria

1. no informed consent
2. palliative treatment

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-03-2008

Enrollment: 28

Type: Anticipated

Ethics review

Approved WMO

Date: 29-10-2008

Application type: First submission

Review commission: METC Amsterdam UMC

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	NL22168.029.08