PRE- MISTIC: MRI and cine Imaging to Improve Staging of Tumors In the Colon.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON57517

Source
Onderzoeksportaal

Brief title
PRE-MISTIC: MRI and cine Imaging to Improve Staging of Tumors In the Colon.

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
Colon carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Derde geldstroom (anders, zoals collectebussenfondsen, Europese Unie, vakministeries of bedrijven)

Intervention

- Other intervention

Explanation

N.a.

Outcome measures

Primary outcome

Main study parameters/endpoints: The main study parameters and endpoints include: - Sensitivity and specificity of different MRI sequences in diagnosing T4 disease compared to the gold standard of histological examination. - Sensitivity and specificity of cineMR and cineCT in diagnosing T4 disease compared to the gold standard of histological examination.

Secondary outcome

- Sensitivity and specificity of different MRI sequences, including diffusion-weighted imaging, in diagnosing N2 disease compared to the gold standard of histological examination. - The number of discrepancies between the clinical staging of T3/T4 disease using dedicated diffusion-weighted MRI and the operative and histological findings.

Study description

Background summary

Clinical staging of colon tumors is increasingly important, especially when considering neo-adjuvant therapy for patients with high-risk tumors (T4 or N2 disease). The current standard work-up using CT and endoscopy is highly inaccurate, with 40% of pathological T4 tumors not being correctly staged as T4 before surgery. MRI sequences and cine imaging hold promise for more accurate staging of colon tumors.

Study objective

The objective of this study is to pilot the feasibility of MRI and cine imaging in improving pre-operative staging of colon tumors. The specific aims of this pilot study are to establish an optimized scanning protocol and provide preliminary diagnostic characteristics that can be used to design a larger trial.

Study design

This is a prospective cohort study.

Intervention

Intervention (if applicable):

Patients will undergo an additional MRI with various sequences and cine imaging (cineMRI and cineCT) prior to surgery.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit, and group relatedness:

Patients participating in the study will be asked to undergo an additional MRI scan (with gadolinium-based contrast fluid, brand name: Dotarem, regular dosage). The estimated scanning time is 40 minutes due to the exploration of different cine sequences. MRI scans are non-invasive and do not involve harmful radiation. Additionally, an additional cineCT scan will be performed with an estimated scanning time of 10 minutes, with iodine contrast material (Iomeron 300, regular dosage). The maximum additional radiation exposure with cineCT with contrast is 8.4 mSv. This radiation dose falls within the range of 1 diagnostic CT scan routinely performed in the diagnostic workup of this patient group. The additional risk associated with this radiation dose is negligible for patients who receive multiple CT scans during diagnostic workup, perioperative care, and long-term follow-up for colon carcinoma. There is no direct benefit to participation in the study. However, there is a very small chance that the additional scans may reveal an incidental diagnosis relevant to the patient's health. Patients who do not wish to be informed about such a diagnosis cannot participate in the study.

Contacts

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Trial sites

Trial sites in the Netherlands

Radboud Universitair Medisch Centrum
Target size: 15

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

The following patients are eligible for inclusion in the study:
- Patients with clinical suspicion for T3 or T4 colon tumor based on standard clinical work-up with endoscopy and CT-scan.
- Age > 18 years
- WHO Performance status of 0-2

Exclusion criteria

Patients who meet any of the following criteria will be excluded from participation in this study:
- Patients with contraindications for MRI
- Patients with clinical contraindications to undergo colon surgery
- Patients receiving neoadjuvant therapy prior to surgery
- Patients with known allergy to iodine or gadolinium contrast

- Patient with contra-indication for contrasts based on kidney failure
Neoadjuvant therapy is currently not the standard of care for advanced colon carcinoma, and applied only in selected cases or as part of a clinical trial. Because neoadjuvant therapy could result in tumor regression, thus impacting the gold standard of histological examination, patients selected for neoadjuvant therapy are excluded from this study.

Study design

Design

Study phase:	N/A
Study type:	Observational invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2024
Enrollment:	15
Duration:	1 months (per patient)
Type:	Anticipated

Medical products/devices used

Product type:	N.a.

IPD sharing statement

Plan to share IPD: Yes

Plan description
N.a.

Ethics review

Approved WMO Date:	28-04-2025
Application type:	First submission
Review commission:	METC Oost-Nederland

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
ClinicalTrials.gov	NCT06216743
Research portal	NL-009921