Optimization of a new MR protocol measuring iron content in gastrointestinal cancer

Published: 28-05-2019
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Translation of MR technique from research to clinical setting.

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal conditions NEC
Study type	Observational invasive

Summary

ID

NL-OMON48263

Source
ToetsingOnline

Brief title
Gastrointestinal tumor iron measurement (GIRON)

Condition

- Gastrointestinal conditions NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
colon cancer with liver metastasis, pancreatic cancer) and with a clinical indication for MR examination, Patients with gastrointestinal cancer (including rectum cancer

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Gastrointestinal tumor, Iron, MRI

Outcome measures

Primary outcome

The results of the additional MR technique are compared with those of conventional MR techniques. The additional MR protocol is evaluated for their added value, points for optimization are identified and these are included in the continuous process of development. Scientifically relevant results from this clinical pilot study will be published.

Endpoints: quantity of iron on T2 * MRI, LIF score, fat fraction

Secondary outcome

Not applicable

Study description

Background summary

MR is a technique that is constantly evolving. One of the potentially new applications of a new MR protocol concerns the measurement of iron levels in the body, and specifically in gastrointestinal tumors. This application appears to be very interesting since scientific research has shown that iron seems to play an important role in almost all aspects of both cancer development and cancer growth. This technique can only be fully optimized in sensitivity and specificity when patient data is available. To promote this MR technique, it is important to conduct a pilot study, specifically in patients presenting with a gastrointestinal tumor who receive an MRI as part of the standard diagnostic procedure. In the future, for example, the MR technique can be used to measure the effect of iron chelation, which is currently investigated as a new anticancer therapy.

Study objective

Translation of MR technique from research to clinical setting.

Study design

Observational. Patient participation implies extension of the clinical MR scan with the additional MR technique. The research concerns the non-invasive assessment of the iron content in gastrointestinal tumors by means of T2 * MRI.

Study burden and risks

MR acquisitions will be added to the conventional clinical MR scans, with a maximum extension of 15 minutes. The new MR technique does not include administration of extra contrast fluid / medication. Additionally, patients will be asked to stay sober 4 hours in advance, and blood will be taken for interpretation of the MR data.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

All patients with gastrointestinal cancer (including rectum cancer, colon cancer with liver metastasis, pancreatic cancer) and with a clinical indication for MR examination

Exclusion criteria

All contra-indications for MR examinations (claustrophobia, cardiac pacemaker, implants not approved for MR at the employed field-strength, metal objects, etc)
Incapable to undergo prolonged MR examinatio n additonal to clinical MR examination (due to frailty of old age, general condition, etc).
No informed consent for notification of study participation to the medical specialist.
No informed consent for the work-up of incidental findings.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2019
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	28-05-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) 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	NL67569.058.18