Dedicated MR imaging vs surgical staging of peritoneal carcinomatosis in colorectal cancer patients; a randomized multicenter trial

Published: 13-09-2019
Last updated: 10-04-2024

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

Summary

ID

NL-OMON52404

Source
ToetsingOnline

Brief title
DISCO

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
metastasis colorectal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis

Source(s) of monetary or material Support: ZonMw,Antoni van Leeuwenhoek-NKI

Intervention

Keyword: colorectal cancer, MRI, peritoneal carcinomatosis, randomized

Outcome measures

Primary outcome

Number of preventable unnecessary laparoscopies and explorative laparotomies

Secondary outcome

-- Number of additional extra-peritoneal findings

- Number of early recurrences (with-in 6 months after R1 resection and HIPEC)

- Diagnostic performance of Peritoneal Cancer Index determined by MRI (MRI-PCI)

to predict surgical Peritoneal Cancer Index (S-PCI).

- Inter-observer agreement between different readers for DW-MRI.

- Incremental costs, effects, and incremental cost-effectiveness ratio.

- Quality of life between diagnostic arms

Study description

Background summary

MRI is a potentially powerful tool to reliably determine the intra-abdominal tumor load and relations with intra-abdominal organs. In recent years diffusion weighted MRI has proven its value as a highly sensitive technique to detect small malignant disease in a wide variety of cancers [1-3]. However, literature concerning the clinical impact of detecting peritoneal metastases with MRI is very limited. Therefore, there is a need for a large randomized multicenter trial to determine whether dedicated MRI can be used as a selection tool for CRS-HIPEC candidates in daily practice.

Study objective

Our goal is to perform a multicenter randomized study to compare a less

invasive diagnostic workup ARM A (with MRI and surgical inspection reserved for borderline operable cases on MRI) to the standard diagnostic workup (ARM B, without MRI, with surgical staging to determine resectability based on a MDT decision) of patients with (suspected) peritoneal metastases. Surgical staging laparoscopies may largely be replaced by MRI (only reserved as a problem solver for borderline operable cases in ARM A). If we can prove that MRI is an accurate, robust and cost-effective staging tool than this will result in a more patient friendly diagnostic workup with less futile surgical procedures.

Study design

Multicenter randomized trial.
Patients, suspected of having colorectal peritoneal metastases and considered for CRS-HIPEC, will be included. Patients will be randomly assigned after inclusion to one of two diagnostic arms towards CRS/HIPEC. In arm A, the experimental arm, patients will undergo dedicated MRI imaging of the pelvis, abdomen, and thorax. In arm B will undergo the current standard diagnostic work-up of DLS at indication (MDT decision) and otherwise continue to CRS-HIPEC.

Study burden and risks

MRI is a standard diagnostic procedure without the use of radiation. The MR sequences, MR-contrast agents and Buscopan (to mimimize peristaltic bowel movements) are all commonly used in daily clinical practice. In addition, patients will be asked to drink 1L of pineapple juice 1 hours before the MRI (to minimize signal in the bowel lumen and optimize image quality), which is standard procedure in many clinics for MRCP and MR enterography. By acting upon the MRI findings in the experimental arm A, could result into new risks as oppose to standard clinical practice. However by introducing the borderline group (*yellow light* group) to receive diagnostic laparoscopy will minimize the possibility of over-staging a patient that would have received a successful CRS/HIPEC in de control arm.

Burden
- Per MRI 35 minutes for MR imaging procedure ,
- 1 hr before the MRI drink 1 ltr of pineapple juice according to standard care.
- 1 (Group B) of 2 (Group A) extra visits for the MRI, total time per visit is expected to be 2 hrs
- For Group A is the total burden is 4 hours as for Group B 2 hours in 8 months
- QOL questionnaire: 3 times, 15 minutes per questionnaire

Risks:
• Gadolinium and Buscopan will be administrated intravenously. A potential side

effect that can occur as a result of the administration is an allergic reaction. Although it is known that the side effects of Gadolinium /Buscopan are limited and occur in only a very limited number of patients, the possibility of serious or life-threatening anaphylactic or anaphylactoid reactions.

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

- Patients with suspicion of colorectal peritoneal metastases and considered for CRS/HIPEC
- Age >18 years
- Written and signed informed consent
- WHO 0-2

- Able and willing to drink 1 liter of pineapple juice

Exclusion criteria

- Patients with contraindications for MRI:
- Patients who have a heart pacemaker may not have an MRI scan
- Patients who have a metallic foreign body (metal sliver) in their body
- Patients with severe claustrophobia
- Ineligibility to receive gadofosveset (Gadolinium) contrast (history of contrast allergy, impaired kidney function with a Glomerular Filtration Rate <30 ml/min/1.73m2)
- Ineligibility to receive Buscopan
- Allergy for pineapple juice and blueberry juice.
- Patients with clinical contraindications for CRS/HIPEC
- Patients with radiological contra-indications for CRS/HIPEC observed on CT thorax/abdomen
- Massive mesenteric or small bowel involvement which would lead to short bowel syndrome if adequately resected
- Extra-peritoneal metastases for which CRS/HIPEC is not justifiable (such as lung metastases, skeletal metastases, and liver metastases)
- Known additional malignancy, unless treated with curative intent at least five years ago. In situ cancers, basal cell carcinoma of the skin or squamous cell carcinoma of the skin that have undergone potentially curative therapy within the past five years may also be eligible.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-11-2019
Enrollment:	192

Type:	Actual

Ethics review

Approved WMO Date:	13-09-2019
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	21-01-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	18-03-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	10-07-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	30-12-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-11-2022
Application type:	Amendment
Review commission:	METC NedMec

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	NL70045.031.19