Clinical impact of dedicated MR staging of ovarian cancer patients

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To determine the diagnostic performance and potential clinical benefit of DW-MRI as a staging tool to identify patients with advanced stage ovarian cancer who can benefit from cytoreductive surgery.

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

Summary

ID

NL-OMON48584

Source
ToetsingOnline

Brief title
MRStagingOC

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
Peritoneal Carcinomatosis, Peritoneal Seeding

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: ZonMw,Antoni van Leeuwenhoek ziekenhuis

Intervention

Keyword: Diffusion Weighted Imaging, Ovarian Cancer, Peritoneal Cancer Index, Peritoneal Carcinomatosis

Outcome measures

Primary outcome

Diagnostic performance of DW-MRI to predict whether complete cytoreductive surgery can be achieved (defined as the number of cytoreductive procedures correctly predicted by DW-DWI).

Secondary outcome

- Diagnostic performance of radiological Peritoneal Cancer Index (rPCI) determined DW-MRI to predict surgical Peritoneal Cancer Index (sPCI).

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

- Diagnostic performance of radiological Peritoneal Cancer Index (rPCI) determined CT to predict surgical Peritoneal Cancer Index (sPCI).

- Comparing the performance of CT and MRI.

- Number of additional *second look* surgical findings due to the per-operative availability of DW-MRI findings

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

Study description

Background summary

Cytoreductive surgery (CRS) is the treatment of choice for peritoneal carcinomatosis (PC). In order to achieve a significant survival gain a complete cytoreduction is essential in the surgical treatment of PC in advanced stage ovarian carcinoma. Whether a complete cytoreduction is feasible is determined by the amount and localization of disease in the abdomen. In ovarium carcinoma

the Peritoneal Cancer Index (PCI) is a scoring system using surgical inspection to assess the amount and localization of disease. This scoring system is used similarly in PCs of other origins, such as colorectal cancer. Currently a diagnostic laparoscopy is often used to inspect all areas in the abdomen and to predict whether a complete cytoreduction is feasible. However, with this invasive procedure it is not always feasible to inspect all relevant areas in the abdomen due to the presence of adhesions and / or tumor. It would therefore be more than helpful if a radiological diagnostic tool could accurately assess the amount and localization of peritoneal disease before any surgery in order to predict the possibility of achieving a complete cytoreduction. Thus far, the accuracy of the radiological diagnostic tools remains limited. A better selection of the group of patients in whom a complete cytoreduction is feasible will limit the number of ineffective procedures; for patients with advanced stage ovarian carcinoma a better diagnostic tool will enable the clinician to decide whether to perform primary cytoreductive surgery or start with neo-adjuvant chemotherapy.
However, current radiologic diagnostic tools are not able to accurately predict the PCI and therewith the chance of performing complete cytoreductive surgery. The most commonly used diagnostic tool is CT, which is known to have limited accuracy in demonstrating the extent of peritoneal seeding. A recent meta-analysis showed a poor pooled sensitivity of 73% for the detection of peritoneal seeding on a patient basis[1].
The superior soft tissue contrast of magnetic resonance imaging (MRI) makes this technique very promising for evaluating peritoneal involvement. An added benefit of MRI is the addition of diffusion-weighted sequences. Diffusion weighted imaging (DWI) is a powerful functional imaging tool for the detection of even small-volume malignant disease. Recently, DW-MRI has shown to be superior to CT in predicting incomplete resection and staging in patients suspected of having ovarian cancer[2]. A few small studies showed improved results in predicting PCI with MRI[3, 4]. Despite these promising results, the role of MRI for staging the peritoneal cavity has not been extensively studied thus far.

Study objective

To determine the diagnostic performance and potential clinical benefit of DW-MRI as a staging tool to identify patients with advanced stage ovarian cancer who can benefit from cytoreductive surgery.

Study design

Prospective observational cohort multi-center study.

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. The only extra burden will be that patients will be asked to drink 1L of pineapple juice 1h 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.

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 advanced stage (FIGO stage III or IV) ovarian cancer scheduled for primary or interval cytoreductive surgery
- Age >18 years

- Written informed consent

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
- Contrast allergy for MRI contrast agent Gadolinium (extremely rare)
- Ineligibility to receive gadofosveset 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 contraindications for CRS
- WHO performance status 3 or higher

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):	04-06-2018
Enrollment:	270
Type:	Actual

Ethics review

Approved WMO

Date:	12-04-2018
Application type:	First submission

Review commission:	METC NedMec
Approved WMO Date:	24-01-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	01-03-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	10-05-2019
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
ClinicalTrials.gov	NCT03399344
CCMO	NL63521.031.17