MR-PET for staging and assessment of operability in ovarian cancer * a feasibility study

Published: 30-12-2014
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Primary Objective: To evaluate the diagnostic performance of MR-PET in preoperative staging and evaluation of operability of women with advanced stage epithelial ovarian cancer. Diagnostic accuracy in terms of sensitivity and specificity of MR-PET...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON44242

Source
ToetsingOnline

Brief title
MR-PET in ovarian cancer

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
ovarian cancer, ovarian neoplasm

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Academisch Fonds

Intervention

Keyword: Cancer staging, MR-PET, Ovarian cancer

Outcome measures

Primary outcome

Main study parameter will be the diagnostic performance of MR-PET in preoperative staging and evaluation of operability of women with advanced stage epithelial ovarian cancer. Different anatomical sites will be evaluated systematically. Numbers of true positive (TP), false positive (FP), true negative (TN) and false negative (FN) will be recorded for each item from which sensitivity, specificity, positive predictive value, negative predictive value and accuracy will be calculated. The index test (MR-PET) will be compared to the current imaging modality of choice in clinical practice (CT). Surgical staging and histopathology will be used as the reference standard.

Secondary outcome

NA

Study description

Background summary

Very recently, the academic hospital Maastricht invested in an integrated MR-PET system (Biograph mMR, Siemens Healthcare, Erlangen, Germany), ready to use for routine clinical application. Applications of this system are numerous and various types of cancer, including ovarian cancer, could benefit from the possibilities. The whole-body MR-PET system integrates the strengths of MRI and PET within a single examination. MRI provides anatomic detail in staging local tumor extent due to its high soft tissue resolution and advanced functional techniques such as DWI further enhance both local and distant lesion detection and characterisation. PET imaging complements this structural and functional information with molecular imaging technology useful in staging of adenopathy

and metastatic spread. These characteristics contribute to a wide spectrum of possible clinical oncological applications, from primary tumor detection to local and distant staging, selection of patients for neoadjuvant therapy and assessment of response to chemotherapy and finally evaluation of recurrent disease.

Study objective

Primary Objective: To evaluate the diagnostic performance of MR-PET in preoperative staging and evaluation of operability of women with advanced stage epithelial ovarian cancer. Diagnostic accuracy in terms of sensitivity and specificity of MR-PET will be compared to the current gold standard, CT imaging. Histopathology in combination with intraoperative findings will be used as the reference standard.

Study design

Prospective pilot study.

Intervention

The MR-PET will be performed with the Biograph mMR system (Siemens Healthcare, Erlangen, Germany). This system integrates a 3Tesla MRI and PET scan which makes simultaneous acquisition of whole-body MRI and PET images possible. The Biograph mMR holds the CE mark and was FDA approved in June 2011. The Biograph mMR is intended to be used in the Academical hospital Maastricht for standard patient care. The radiotracer that will be used is 18F-labeled fluorodeoxyglucose (18F-FDG), according to standard PET-protocol.

Study burden and risks

The burden for patients exists of 1 MR-PET scan, total time: 60 minutes. Radiation exposure is low and MR-PET is safe for patients with no contra-indications to MRI. Patients with contra-indications will be excluded for participation in this study.
Risks associated with undergoing MR-PET are claustrophobia and self-inflicted injuries due to this claustrophobia, bleeding or burns in case of presence of metal objects, tinnitus, dizziness and balance disorders.
The side effects of MRI contrast agent (Gadovist) are rare: nausea, vomiting, urticaria, feeling of warmth, wheals (localized itchy oedema), dizziness, cough, dyspnoea, severe anaphylactic reaction occur in less than 0,5% of cases.
Venipuncture/peripheral catheter insertion for administration of the PET tracer and MRI contrast agent is rather safe and is part of routine patient care. The occurrence of a local redness cannot be excluded.

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

Expected FIGO stage IIB-IV epithelial ovarian carcinoma
Scheduled for primary debulking surgery or interval debulking surgery
Written informed consent
At least 18 years of age.

Exclusion criteria

Patients estimated to have more benefit from (neoadjuvant) chemotherapy
Ineligibility to undergo MR-PET examination:
- Non-MR compatible metallic implants or foreign bodies (ferromagnetic aneurysm clip, pacemaker, neurostimulation system, metal splinters etcetera).

- Claustrophobia
Pregnant or lactating patients.
Incapacitated subjects

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-04-2015
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	MR-PET
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	30-12-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	20-05-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit

	Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	12-10-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	31-05-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL50080.068.14

Study results

Date completed:	22-04-2016
Actual enrolment:	10