18F-FDG PET-MRI in patients with uterine cervical cancer - PETRA-C

Published: 05-09-2014
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Feasibility of 18F-FDG PET-MRI in inoperable uterine cervical cancer.

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

Summary

ID

NL-OMON41355

Source
ToetsingOnline

Brief title
PETRA-C

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
uterine cervical cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Academisch Medisch Centrum,Gedeeltelijk gefinancieerd door Philips Medical Solutions,Philips Research

Intervention

Keyword: PET-CT, PET-MRI, uterine cervical cancer

Outcome measures

Primary outcome

1. Practical aspects of 18F-FDG PET-MRI protocol (e.g. imbedding of our current MRI protocol in the PET-MRI protocol, presence of artifacts, optimal patient preparation)

2. Assessment of the primary tumor: size and FDG uptake on 18F-FDG PET-MRI versus 18F-FDG PET-CT)

3. Lymph node visualisation on 18F-FDG PET-MRI versus 18F-FDG PET-CT (pelvic and paraaortal)

4. Patient comfort during 18F-FDG PET-MRI versus 18F-FDG PET-CT

5. Detection of distant metastases

6. The possibilities of PET-MRI based radiation treatment planning in a PET-MRI system not specially equipped with radiotherapy treatment facilities will be explored.

Secondary outcome

n.a.

Study description

Background summary

The official staging of cervical cancer is primarily based on clinical findings of the primary tumor (FIGO-staging)1. However, it has been shown that prognosis is also strongly correlated with tumor size2, the FDG-uptake of the tumor3 and lymph node involvement4. Thus, when available, imaging is done to assess exact tumor size, parametrial and adjacent organ invasion, and lymph node status5. MRI is the first choice in imaging uterine cervical cancer due to its good performance showing the primary tumor and invasion in parametrial and adjacent tissue6. 18F-FDG PET-CT is less accurate in determining exact tumor size and

parametrial invasion but performs well in case of nodal and distant metastases7. Both MRI and 18F-FDG PET-CT show an accuracy round 80% in detecting locoregional and paraaortal lymph node metastases8.
The first choice for curative treatment in inoperable cervical cancer (stage IIB or higher) is (chemo) radiation9. Nowadays it is possible to equip the PET-CT with radiation treatment planning requisites, providing information on staging and radiotherapy treatment planning in one investigation. This relatively new approach is standard care in the AMC since 2008.
Recently, the first clinical PET-MRI facility was installed in the Netherlands (VUMC). Given the above-mentioned complementary role of 18F-FDG PET-CT and MRI in uterine cervical cancer, the combination of these two imaging modalities in one PET-MRI investigation could result in a higher diagnostic power with less radiation burden and improved patient comfort.
There are preliminary data on software fusion of separate 18F-FDG PET-CT and MRI investigations to achieve a complete dataset for tumor and metastasis assessment as well as for treatment planning11. However, the combined 18F-FDG PET-MRI in one session has not been studied yet in patients with inoperable uterine cervical cancer.
In this study, patients will undergo 18F-FDG PET-CT in radiotherapy treatment setting, followed by 18F-FDG PET-MRI. To perform both procedures, PET-CT and PET-MRI, the same dose of 18F-FDG will be used without additional administration of FDG.

Study objective

Feasibility of 18F-FDG PET-MRI in inoperable uterine cervical cancer.

Study design

In this study, patients will undergo 18F-FDG PET-CT in radiotherapy treatment setting, followed by 18F-FDG PET-MRI. To perform both procedures, PET-CT and PET-MRI, the same dose of 18F-FDG will be used without additional administration of FDG.
After the PET-MRI patients will be asked to fill in a questionnaire.

Study burden and risks

Patients undergo a PET-MRI investigation after 18F-FDG PET-CT, with an additional scan time of approximately 60 minutes. There is no additional administration of 18F-FDG, hence no additional radiation burden in that sense. Two very low dose CT scans are going to be added to the scanprotocol to assist attenuation correction, maximal additional radiation burden will be 4,6mSv.
Since the PET-MRI is located in the VU medical center, patients will undergo PET-CT and PET-MRI in the VUmc instead of the AMC. This could mean some additional travel time.
After the PET-MRI patients will be asked to fill in a questionnaire.

In the future, one 18F-FDG PET-MRI investigation might be sufficient for appropriate staging and radiotherapy treatment planning instead of the current situation when an MRI and a PET-CT is separately performed. This means one visit to the imaging department instead of two, a reduction in total scan duration of approximately 30 minutes and a reduction in radiation burden up to 20 mSV compared to the current standard care at our institution. Importantly, this setup will result in a perfect match of MRI and PET acquisitions, preventing current uncertainties in correlating the findings in both examinations.

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 > 18 years

Inoperable cervical cancer, FIGO stage IIb or higher, based on the investigation under anaesthesia
Treatment plan: (chemo) radiation with curative intent
Informed consent

Exclusion criteria

Tumor relapse
Conisation or lymph node dissection in the past
Claustrophobia, pregnancy, fasting serum blood sugar >10mmol/l, morbid obesity, standard MRI contraindications and joint prosthesis (as possible cause of attenuation artefacts on PET-CT or PET-MRI)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-11-2016
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	05-09-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	29-05-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-05-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL47133.018.13