18F-FDG PET/CT versus CT imaging in staging of primary Muscle Invasive Bladder Cancer

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The purpose of this prospective study is to evaluate the value of 18F-FDG PET/CT and CT for preoperative regional N staging of bladder cancer and to verify the results by comparison with histopathological analysis, the gold standard.

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

Summary

ID

NL-OMON43864

Source
ToetsingOnline

Brief title
MIBC PETCT

Condition

- Renal and urinary tract neoplasms malignant and unspecified

Synonym
bladder cancer, urothelial cell carcinoma

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: CT, MIBC, PET-CT, TNM staging

Outcome measures

Primary outcome

To evaluate the predictive accuracy of 18F-FDG PET/CT in comparison to conventional work-up with contemporary CT scan for the preoperative detection of nodal metastases in patients with invasive T2-T3 bladder cancer through detailed comparison of CT imaging and pathologic findings following radical cystectomy.

To test differences in diagnostic performance between the 2 imaging procedures for significance by the paired sample comparison with a significance level of .05 and a power of 0.8 superiority of PET/CT over CT will be determined aiming at an improvement of 10% in specificity and/or an improvement of 10% in sensitivity (PET/CT being superior). Sensitivities, specificities, negative predictive values, positive predictive values, and accuracies (with exact 95% confidence intervals [CIs]) for both modalities will be determined for detection of metastases to lymph nodes as well as for distant metastases.

Secondary outcome

- To identify the extent to which FDG-PET/CT results may affect clinical decision making in patients with muscle-invasive bladder cancer.

- To identify whether PET/CT is better in detecting (possible) distant metastases than contemporary diagnostic CT.

- To test the difference in accuracy between PET/low dose CT (without contrast)

versus PET/high dose CT (with oral and intravenous contrast).

- To collect tissues from primary tumour and lymph nodes for research on

bladder cancer in general and more specifically to investigate which

tumour and lymph node characteristics relate to clinical staging, and 2 year

cancer-specific outcome.

Study description

Background summary

Accurate pre-operative and post-operative tumour staging in most cancers is of essential importance for decision-making and prognostic classification. FDG PET/CT has been demonstrated to have good sensitivity and specificity in the detection of metastatic disease in malignancies and provide additional diagnostic information that enhances clinical management more than CT or MRI alone. Combined PET/CT is now widely used for tumour staging. In a number of malignancies it has been shown that PET/CT staging with FDG is significantly more accurate than PET alone, and side-by-side PET and CT.
Bladder cancer is the most frequent tumour of the urinary tract and the 9th most common cancer diagnosis worldwide. Estimated incidence is more than 330,000 new cases per year and more than 130,000 deaths per year worldwide. In bladder cancer, relatively few imaging studies have been performed with FDG PET alone. In current practice, PET/CT is routinely used in many centers worldwide either alone or in combination with high resolution, contrast enhanced CT as diagnostic modality for the preoperative staging of muscle invasive bladder cancer. The standard imaging work up in most Western European countries already includes PET/CT although its superiority compared to CT alone has not unequivocally been demonstrated. Within countries the approach may differ between centers based on local criteria including availability of PET/CT.
In the present study combined 18F-FDG PET/CT scans will be performed in all of the patients in order to assess the added value of PET/CT imaging. The results of this large study will either result in evidence based level 1 evidence of current practice of using PET/CT in preoperative staging of patients considered for cystectomy (scientific assessment of level of evidence) or to omit PET/CT in the current standard work up policy of many centers (efficiency outcome and implications for health economics).

Study objective

The purpose of this prospective study is to evaluate the value of 18F-FDG

PET/CT and CT for preoperative regional N staging of bladder cancer and to verify the results by comparison with histopathological analysis, the gold standard.

Study design

Prospective observational study among patients with a clinical diagnosis of muscle invasive bladder cancer with active disease identified within the bladder at the time of consent and imaging.

To elucidate the role of FDG PET/CT in the clinical management of muscle-invasive bladder cancer and to assess a 10% difference in specific and/or sensitivity of PET/CT over conventional work up with CT.

Procedure: CT scan, and FDG PET/CT scan. The surgeon will remain blinded for the outcome of the PET/CT scan until after the operation. Patients will be scheduled for surgery to remove their bladder and lymph nodes according to the template LND as described in section 4.2 within 6 weeks after the CT and FDG PET/CT imaging. Since conventional workup includes only a CT scan and since the surgeons will operate and remove lymph nodes from different anatomical regions according to a well-defined consensus template procedure, the patient will receive optimal care according to current guidelines. Therefore, pre-operative knowledge of the surgeon with regard to the outcome of PET/CT may result in a bias and the statistically rigorous value of the outcome of the trial will be jeopardized. It is thus fully justified that there will be no knowledge of the PET/CT readings prior to surgery to avoid biased decision making which is not in agreement with the design of the study.

To test differences in diagnostic performance between the 2 imaging procedures for significance by the paired sample comparison with a significance level of .05 and a power of 0.8 superiority of PET/CT over CT will be determined aiming at an improvement of 10% in specificity and/or an improvement of 10% in sensitivity (PET/CT being superior). Sensitivities, specificities, negative predictive values, positive predictive values, and accuracies (with exact 95% confidence intervals [CIs]) for both modalities will be determined for detection of metastases to lymph nodes as well as for distant metastases.

Study burden and risks

The benefits for both participants and future patients certainly outweigh the burden placed upon the participants by the extra FDG PET/CT that will be performed in addition to standard care and the 2 extra blood samples that will be collected at the time of routine blood collection for standard clinical procedures.

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 a clinical diagnosis of muscle invasive bladder cancer with active disease identified within the bladder at the time of consent and imaging.
-Patients with primary resectable tumour in the bladder, clinically suspect of invasive bladder carcinoma, who are potential candidates for radical cystectomy plus lymphadenectomy, will be eligible with residual disease in the bladder at the time of imaging.
-All patients will have consented to diagnostic imaging procedures.

Exclusion criteria

- Prior biopsy of the primary bladder tumour within 6 months before PET/CT imaging
- Prior BCG instillations.

- Treatment with bladder instillations other than with BCG less than 6 months ago
- Patients with sarcoidosis, tuberculosis and/or lymphatic disorders
* Prior pelvic radiation for bladder cancer
- Patients deemed not appropriate surgical candidates
- Patients that cannot tolerate being in the PET scanner or deemed unable to receive a contrast enhanced CT.
- Patients who are pregnant or lactating

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):	21-01-2014
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	15-03-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	03-02-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO Date:	10-03-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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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	NL42733.058.12