Quantitative FDG-PET/CT of primary bladder cancer

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This study aims to evaluate different techniques for emptying, flushing and filling of the bladder using a bladder catheter in a pilot study, to find and standardise the best technique. This will make FDG-PET/CT suitable for response monitoring of (...

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

Summary

ID

NL-OMON33365

Source
ToetsingOnline

Brief title
Quantitative FDG-PET/CT of primary bladder cancer

Condition

- Renal and urinary tract neoplasms malignant and unspecified
- Bladder and bladder neck disorders (excl calculi)

Synonym
Bladder cancer, bladder carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Uit afdelingsbudget nucleaire geneeskunde NKI-AVL

Intervention

Keyword: Bladder cancer, Bladder catheter, FDG-PET/CT

Outcome measures

Primary outcome

The best technique for visualisation and quantification of bladder cancer with

FDG-PET/CT, and standardisation thereof.

Secondary outcome

none.

Study description

Background summary

Primary bladder cancer cannot be visualised or quantified using FDG-PET/CT due to the presence of excreted FDG in the bladder. Delayed imaging and forced diuresis have insufficient effect. Flushing and filling of the bladder with a bladder catheter has been described and is effective, but the procedure has never been standardised. Differences in bladder volume and residual FDG after flushing and filling hamper the measurements. Therefore, standardised visualisation and quantification is not an option at this moment, and therefore response evaluation of chemotherapie is not reliably possible.

Study objective

This study aims to evaluate different techniques for emptying, flushing and filling of the bladder using a bladder catheter in a pilot study, to find and standardise the best technique. This will make FDG-PET/CT suitable for response monitoring of (neoadjuvant) chemotherapie for primary bladder cancer in future patients.

Study design

Ten patients will undergo FDG-PET/CT while FDG containing urin is removed from the bladder with a bladder catheter, using four different strategies for flushing and filling. The technique that yields the best visualisation and the most reliable quantification will be determined using visual evaluation and

standardised uptake value (SUV) measurements.

Study burden and risks

Limited risk of bladder catheter placement and one intravenous injection. The radiation burden of one FDG-PET/CT scan is not considered a significant risk.

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

1. Histology proven bladder cancer
2. Untreated, primary evaluation
3. cT2-4 Nx Mx

Exclusion criteria

1. Contra-indication for bladder catheter
2. Pregnancy or breastfeeding
3. Age < 18 years
4. Restricted water intake

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2009
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL27877.031.09