BioXmark liquid fiducial markers for image guided radiotherapy in bladder cancer, a safety and performance trial

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This study will evaluate usability, safety and performance of a cystoscopic guided injection of a marker (BioXmark) at the tumor site in patients with bladder cancer on planning CT and CBCT during the irradiation period.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal and urinary tract neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON46787

Source
ToetsingOnline

Brief title
BioXmark, bladder safety and performance trial

Condition

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

Synonym
Bladdercancer, urothelial carcinoma of the bladder

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bladder cancer, IGRT, Radiotherapy, Treatment

Outcome measures

Primary outcome

Primary endpoint:

* Percentage of BioXmark liquid fiducial markers which are visible and remain in a stable position from the CT acquisition for RT planning to last CBCT

Primary safety endpoint:

* Number of adverse events potentially associated with application of BioXmark liquid fiducial markers

Secondary outcome

Secondary endpoints:

* Percentage of markers lost from injection to the CT acquisition for RT planning
* Percentage of patients in which markers can be used for target delineation
* Percentage of patients in which markers can be used for patient set-up

Explorative endpoints:

* Time needed and easiness of application procedure of BioXmark liquid fiducial marker
* Possibility of using BioXmark liquid fiducial markers for automatic online

matching

Study description

Background summary

Radical chemoradiotherapy for patients with muscle-invasive bladder cancer is becoming accepted as a viable treatment option with good long-term outcomes. However, a high dose radiation exposure can damage normal tissue and cause radiotherapy related toxicity. In order to increase precision of the treatment, image guided radiotherapy aided by fiducial markers will be a major benefit, on one hand by sparing small bowel and uninvolved bladder and on the other hand by increased accuracy of the gross tumor radiation. Traditional gold fiducial markers are safe and feasible to apply, however, the procedure is time consuming and literature showed that up to 40% of the gold seeds are lost in verification imaging (mostly kV cone beam CT (CBCT). Liquid markers, such as hydrogel and Lipiodol, are also shown to be safe and feasible to apply. However, the biggest disadvantage of these liquid markers is fading (hydrogel) or blurring (Lipiodol) of the liquid marker spots in the perivesical fatty tissue, leading to inaccurate delineation of the tumor borders and impaired usage of the spots during daily positioning verification on the treatment machine. Furthermore, for accurate Lipiodol implantation (not too much and not too less), fluoroscopy is needed during the endoscopical implantation. This study will evaluate a novel liquid marker, BioXmark, which has the potential benefit of stable visibility without blurring properties combined with simple application.

Study objective

This study will evaluate usability, safety and performance of a cystoscopic guided injection of a marker (BioXmark) at the tumor site in patients with bladder cancer on planning CT and CBCT during the irradiation period.

Study design

This study is a prospective non-randomized open label trial.

Intervention

Injection of at least 3 liquid fiducial markers (BioXmark) in the bladder wall cranial, lateral and caudal (optional) of the macroscopic tumor during cystoscopy.

Study burden and risks

The patient will directly benefit from participation in the study. The markers will be used for tumor delineation and positional verification in each patient.

For this study extra risks compared to the standard procedure are not to be expected. Like all other endoscopic procedures a bleeding or perforation could occur (overall risk < 1%). The infection risk is estimated low, comparable as the bleeding risk, which is also estimated low and the same or lower than the risk related to biopsy procedures. Should bleeding occur it is assumed to be small and self-limiting. The liquid marker used has been demonstrated to be biocompatible in accordance with regulatory requirements for medical devices (EN ISO10993).

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 15
Amsterdam 1100 DD
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 15
Amsterdam 1100 DD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Patients with histologically proven primary bladder cancer
* Referred for bladder conserving (chemo-)radiotherapy in the AMC

Exclusion criteria

* Any contraindication for an cystoscopic procedure
* Pregnant women
* Age < 18 years

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-07-2018
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	BioXmark
Registration:	No

Ethics review

Approved WMO Date:	11-06-2018
Application type:	First submission
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

ID: 23138
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL65305.018.18
OMON	NL-OMON23138