Feasibility study of high field 3.0T multiparametric magnetic resonance imaging for local staging of invasive urinary bladder tumours

Published: 30-05-2018
Last updated: 17-04-2024

-To demonstrate the value of MRI in the initial staging of bladder tumours-To evaluate the feasibility of the use of MRI to delineate bladder tumours for planning GTV for external beam radiotherapy

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

Summary

ID

NL-OMON47494

Source
ToetsingOnline

Brief title
MRI-Bladder

Condition

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

Synonym
Bladdercancer; Bladder tumour

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Roche

Intervention

Keyword: Blaastumour, MRI-scan, Staging

Outcome measures

Primary outcome

-Radiological bladder tumour stage (T-stage) based on MRI-scan

-Pathological bladder tumour stage based on histo-pathology after radical

cystectomy

-Evaluation of *virtual* GTV-planning of the bladder tumour based on MRI

Secondary outcome

none

Study description

Background summary

Several imaging techniques may be used to further specify the extent of the local tumour, e.g. ultrasound of the bladder, CT-urography (CT-IVU) or magnetic resonance imaging (MRI). The CT-scan may give a reasonable impression on the tissue surrounding the bladder and potential lymphadenopathy but is insufficient to adequately stage the primary bladder tumour. In recent years some studies have reported an improvement of local bladder tumour staging, by means of magnetic resonance imaging (MRI).
Currently the planning of external beam radiotherapy (EBRT) for bladder tumours is based on CT-imaging. To increase the accuracy of GTV planning, MRI may be used. Furthermore, in the near future, the use of the MRI-Linac system for real time and on-line MRI guidance of external beam radiotherapy may be used for correction of bladder movement during radiotherapy.

Study objective

-To demonstrate the value of MRI in the initial staging of bladder tumours
-To evaluate the feasibility of the use of MRI to delineate bladder tumours for planning GTV for external beam radiotherapy

Study design

This is an observational study to analyse bladder tumour staging with multiparametric magnetic resonance imaging in patients with a known bladder tumour, who are planned for radical cystectomy.
Patients will be accrued during their visit to the outpatient department of urology. They will undergo the routine laboratory tests (including serum Creatinin) and CT-IVU investigations and subsequently a multiparametric MRI-scan.

Study burden and risks

Prior to surgery a diffusion weighted contrast enhanced 3-Tesla MRI-scan will be made.
The risks and burden are minimal.

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 with an invasive bladder tumour that are scheduled for radical cystectomy

Exclusion criteria

Patients who meet exclusion criteria for MRI following the protocol of the radiology department of the UMC Utrecht

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):	16-08-2018
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	30-05-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	15-08-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL49868.041.16