The IMAGE1 S* Non-Muscle-Invasive bladder cancer study:
A multicenter international randomized controlled study to compare the outcome using the IMAGE1 S* System versus White Light Imaging (WLI) during TURB of Non-Muscle-Invasive Bladder Cancer (NMIBC).

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To compare the recurrence rate of tumor at 12 months following IMAGE1 S* assisted TURB (Arm A) with White Light Imaging only assisted TURB (Arm B) in patients with primary or recurrent non-muscle-invasive urothelial bladder cancer (NMIBC Ta/T1/CIS...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bladder and bladder neck disorders (excl calculi)
Study type	Interventional

Summary

ID

NL-OMON47283

Source
ToetsingOnline

Brief title
IMAGE1 S* bladder cancer study

Condition

- Bladder and bladder neck disorders (excl calculi)
- Renal and urinary tract therapeutic procedures

Synonym
bladder cancer

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, IMAGE1 S□, recurrence, White light

Outcome measures

Primary outcome

Comparison of the proportions of Arm A and Arm B subjects that have a histologically confirmed recurrence found at either three months, one year and three years after TURB.

Secondary outcome

Peri-operative morbidity (30 days) assessed by the Clavien-Dindo score

Proportion of re-TUR (defined as within 3 months of initial TURB: this can be a planned TURBT because of resection of high risk tumor, or because of recurrent tumor confirmed at cystoscopy at three months)

Baseline characteristics of the patients, such as age or BMI

Comorbidities, such as Diabetes Mellitus or cardiovascular disease

Risk factors, such as smoking and use of anticoagulation

When appropriate: information on previous (adjuvant) treatment, such as type and date of most recent treatment and re-TURs

Study description

Background summary

Diagnostics of urothelial cancer (UC) of the bladder is usually performed by the visual approach including the need for biopsies or transurethral resection of the bladder (TURB). Most tumors can be identified by White Light (WL) cystoscopy. However, especially Carcinoma in situ (CIS) is difficult to identify using this procedure. Non-identified tumors can later appear as recurrence, some of which becoming invasive. This demonstrates the need for a procedure that more accurately detects bladder tumors. Since a more accurate detection of tumors leads to more targeted treatment and more complete resection, the rate of recurrence may decrease with such procedures.

KARL STORZ has developed a new technique that is now ready for clinical evaluation. With the IMAGE1 S* System, no endoscopic filter is needed to enhance the image in order to gain more clarity. IMAGE1 S* is based on a new software platform, which uses the different light wavelengths to produce images with different contrast specifications. IMAGE1 S* offers a technique which could be useful in bladder cancer treatment, since clearer images are likely to result in reducing the numbers of tumors that are missed compared with the gold standard White Light Imaging (WLI). Additionally, once the tumor is detected, IMAGE1 S* images may help find the demarcation between tumor and healthy tissue, resulting in more complete resection of the tumor(s). The recurrence rate is expected to be decreased with the use of IMAGE1 S* by obtaining a more complete resection, meaning the patient will need less invasive diagnostic and surgical visits.

Study objective

To compare the recurrence rate of tumor at 12 months following IMAGE1 S* assisted TURB (Arm A) with White Light Imaging only assisted TURB (Arm B) in patients with primary or recurrent non-muscle-invasive urothelial bladder cancer (NMIBC Ta/T1/CIS).

Study design

This study is a multicenter randomized controlled trial in which the recurrence rates of cancer between IMAGE1 S* assisted and WLI assisted TURB are compared. Randomization is stratified by tumor multiplicity (single or multiple), tumor status (primary or recurrent) and macroscopic findings (papillary or flat, where CIS is scored as flat lesion). Patients randomized into the experimental arm (Arm A) will undergo IMAGE1 S* and WLI assisted TURB, whereas the patients in the control arm (Arm B) will undergo WLI only assisted TURB. WLI is chosen as control, since it is considered the gold

standard for detecting bladder tumors. Short and long term follow up will be recorded in order to evaluate the health gains for patients over a longer period.

Each participating center must submit this protocol to their local MEC and each participating center is responsible for the insurance of their patients. Data from all participating centers will be collected through electronic Case Report Forms, with use of an online Data Management System.

Intervention

IMAGE1 S* + WL assisted TURB (experimental arm) vs WL only assisted TURB (control arm)

Study burden and risks

The risks patients are subject to in this trial do not differ from risks associated with non-experimental surgery for this condition. Patients will receive the standard treatment in addition to the extra care that is provided to them in the framework of this study. Patients in the experimental arm could have added value from imaging with use of IMAGE1 S* , since it is expected to improve the sensitivity of the diagnostic tool for assessing bladder cancer.

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 scheduled for treatment of a primary or recurrent NMIBC
Patients aged 18 years or older
Has or has had no tumors in the upper urinary tract
Has had no previous irradiation of the pelvis

Exclusion criteria

Gross haematuria at the time of TURB (i.e. heavy bladder bleeding resulting in marked amounts of blood in the urine which may interfere with cystoscopy)
Pregnancy or breast-feeding (all women of child-bearing potential must document a negative serum or urine pregnancy test at screening and are suggested to use the contraceptive pill or an intrauterine device (IUD) during the treatments and for at least one months thereafter)
Has had instillation therapy in the six months prior to the screening visit

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-04-2015
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	IMAGE1 S imaging software
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	28-01-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-01-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-08-2018
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	NL50451.018.14