The Global randomized NBi bladder cancer study
A Multi-Centre, International study to compare the use of Narrow Band Imaging (NBI) versus White light (WL) to assess recurrence of bladder cancer in terms of safety and efficacy.

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To compare the recurrence rate at 1 year following Narrow Band Imaging and TURB (Arm A) with White Light Trans Urethral Resection of Bladder cancer (TURB) (Arm B) in patients with bladder cancer (NMIBC).The purpose of this study is to investigate...

Ethical review	-
Status	Pending
Health condition type	Bladder and bladder neck disorders (excl calculi)
Study type	Interventional

Summary

ID

NL-OMON34696

Source
ToetsingOnline

Brief title
NBI vs White light TURB

Condition

- Bladder and bladder neck disorders (excl calculi)

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, NBI, recurrence, White light

Outcome measures

Primary outcome

All lesions must be histological confirmed.

The proportion of subjects with histology-confirmed tumors (Ta or T1) who have

at least one such tumor found by NBI but not by white light cystoscopy.

Comparison of the proportions of Group A and Group B subjects who undergo TURB

for a histology-confirmed Ta or T1 tumor who have a recurrence (histology

confirmed Ta or T1) found at either three or twelve months

Secondary outcome

To assess the persistence/recurrence of tumour at first follow up (3 months)

after Narrow Band Imaging and TURB or White Light TURB in patients with NMIBC.

To assess the peri-operative morbidity (30 days) of TURB between NBI and WL

resection by using the Clavien score

To define risk factors for the development of peri-operative morbidity after

instrumental treatment.

To assess the recurrence rate related to the surgeon performing the procedure

To assess the recurrence rate related to additional treatment following TURB.

Study description

Background summary

The standard in diagnostics of UC of the bladder is the visual approach including the need for biopsies or transurethral resection. These invasive procedures provide good results for bladder tumours (cystoscopy and transurethral biopsies/resection). Although most of the bladder tumours can be identified with white light cystoscopy, it has been shown that especially in high-grade tumours areas of carcinoma in situ are missed . And in case of a positive urinary cytology without visual abnormalities, so-called random biopsies have to be taken to demonstrate the presence of carcinoma in situ. Undetected tumours can later appear as a recurrence, and some might become invasive, highlighting the need to develop alternative endoscopic methods to detect bladder lesions more accurately. A more complete identification may at the very least render the bladder more receptive to successful intravesical therapy , and more importantly, may allow for greater detection of high grade/stage tumours, which may alter treatment decisions
The use of photodynamic agents e.g. HEXVIX has been shown to be helpful in these cases in order to accomplish a better resection, identify *overlooked* tumours, and to target biopsies in case of a positive cytology only. This translates in more complete resection, reducing the recurrence rate of non-invasive tumours and in more appropriate treatments .
Another new development in imaging is the narrow band cystoscopy. This technique has been developed by Olympus and is now ready for clinical evaluation in Urology. Narrow Band Imaging (NBI) is a high-resolution endoscopic technique that enhances the fine structure of the mucosal surface without the use of dyes. NBI is based upon the phenomenon that the depth of light penetration depends on its wavelength; the longer the wavelength, the deeper the penetration. Blue light penetrates only superficially, whereas red light penetrates into the deeper layers. The first prototype NBI system (Olympus Corp, Tokyo, Japan) is based upon a light source with sequential red, green, and blue (RGB) illumination. NBI has been investigated in several gastro-enterological diseases and this technique has shown to be beneficial. In Urology there is limited experience for the role of NBI in detecting bladder cancer but early results are promising . However, NBI may have most utility in the operating theatre where a more thorough primary tumour resection may be achievable, as well as reducing the number of tumours that are missed. This could impact the subsequent recurrence rate, resulting in patients experiencing fewer cystoscopic/biopsies/TUR procedures during their disease course, and ultimately leading to a better quality of life and a reduction in the cost of their care.

Study objective

To compare the recurrence rate at 1 year following Narrow Band Imaging and TURB (Arm A) with White Light Trans Urethral Resection of Bladder cancer (TURB) (Arm B) in patients with bladder cancer (NMIBC).

The purpose of this study is to investigate further the value of Narrow Band Imaging (NBI) cystoscopy during surgery compared with white light cystoscopy (WL).White light cystoscopy is currently a standard procedure for removing bladder cancers. Narrow Band Imaging (NBI) is a new endoscopic technique using a special light filter resulting in a high contrast resolution of the mucosa and small vascular structures increases. For this technique, special instruments were developed, with the push on a button during the operation the surgeon can change from WL to NBI. This could provide better sight of the bladder cancer during the surgery. If you see the cancer better, the surgery can be performed better

Study design

This study is a randomized multi-center study to compare the safety (morbidity) and efficacy between NBI assisted TURB and WL assisted TURB. Each participating center must submit the protocol to their local MEC and each participating centre is responsible for the insurance of their patients. The Academical Medical Center in Netherlands is only responsible for the patients that are treated in their hospital.

Intervention

NBI vs white light

Study burden and risks

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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/recurrent NMIBC
Patients should be aged 18 years or older
No tumours in the upper urinary tract
No previous irradiation of the pelvis

Exclusion criteria

Gross hematuria at the time of TURB. (Note: Gross hematuria is defined as a heavy bladder bleeding resulting in marked amounts of blood in the urine, which may interfere with cystoscopy).
Participation in other clinical studies with investigational drugs either concurrently or within the last 30 days.
* Pregnant (all women of child-bearing potential must document a negative serum or urine pregnancy test at screening and use the contraceptive pill or intrauterine device (IUD) during the treatments and for at least one month thereafter).

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2010
Enrollment:	20
Type:	Anticipated

Ethics review

Not available

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	NL31983.018.10