THE GLOBAL RANDOMIZED NBI BLADDER CANCER STUDY -A Multi- Centre, International study to compare use of Narrow Band Imaging (NBI) versus White light (WL) during TURB to assess recurrence of bladder cancer in terms of safety and efficacy.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20575

Source
NTR

Brief title
CROES NBI STUDY

Health condition

Bladder cancer

Sponsors and support

Primary sponsor: Clinical Research Office of the Endourological Society (CROES)
Source(s) of monetary or material Support: Olympus

Intervention

Outcome measures

Primary outcome

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 non muscle invasive (NMIBC Ta/T1) bladder cancer.

Secondary outcome

1. To assess the recurrence of tumour at first follow up (3 months) after Narrow Band Imaging and TURB or White Light TURB in patients with NMIBC;

2. To assess the peri-operative morbidity (30 days) of TURB between NBI and WL resection by using the Clavien score;

3. To define risk factors for the development of peri-operative morbidity after instrumental treatment;

4. To assess the recurrence rate related to the surgeon performing the procedure;

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

Study description

Background summary

A 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- intestinal 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 non muscle invasive (NMIBC Ta/T1) bladder cancer.

Study design

The study consists of a screening evaluation followed by cystoscopy/TURB/biopsies and two follow up cystoscopic examinations at three and twelve months after the initial cystoscopy/TURB/biopsy at least depending on stage and grade of the tumour(s). Since it is not always possible to schedule the follow up visits at exactly three and twelve months, a window of plus/minus two weeks will be accepted. However, the Steering Committee recommends a follow up period of 24 months.

Intervention

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.

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Eligibility criteria

Inclusion criteria

1. Signed informed consent;

2. Patients scheduled for treatment of a primary NMIBC;

3. Patients should be aged 18 years or older;

4. No tumours in the upper urinary tract;

5. No previous irradiation of the pelvis.

Exclusion criteria

1. 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);

2. Participation in other clinical studies with investigational drugs either concurrently or within the last 30 days;

3. 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);

4. Conditions associated with a risk of poor protocol compliance.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2010
Enrollment:	1000
Type:	Actual

Ethics review

Positive opinion Date:	02-10-2012
Application type:	First submission

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
NTR-new	NL3513
NTR-old	NTR3645
Other	CROES : 072010
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A