

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.

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20575

Bron
NTR

Verkorte titel
CROES NBI STUDY

Aandoening

Bladder cancer

Ondersteuning

Primaire sponsor: Clinical Research Office of the Endourological Society (CROES)

Overige ondersteuning: Olympus

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoekopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-08-2010
Aantal proefpersonen:	1000
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	02-10-2012

Soort:

Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3513
NTR-old	NTR3645
Ander register	CROES : 072010
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A