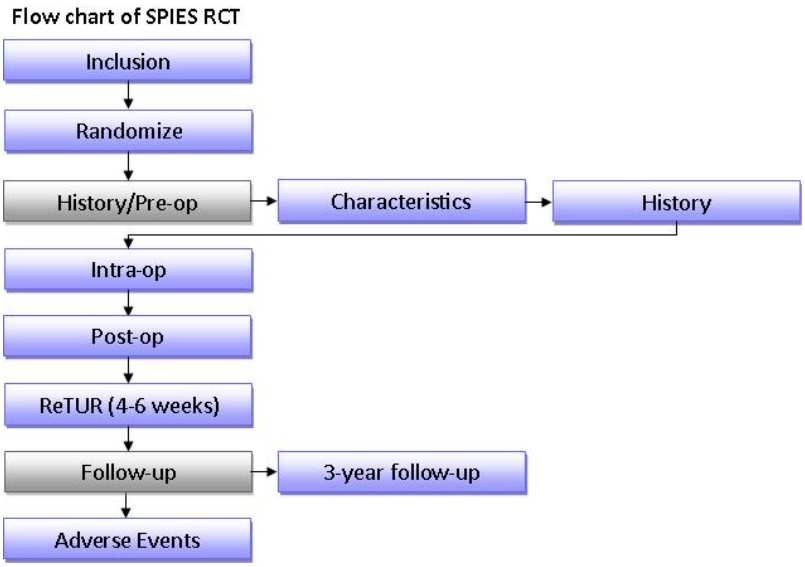
Getting started DMS

Structure of the database



Study procedure

Diagnosis and Pre-treatment evaluation – Visit 1

Patients eligible for screening will be informed about this study as soon as they are being scheduled for TURB. Pre-treatment evaluation at Visit 1 will only be performed after the patient has agreed to participate and has signed and dated the informed consent form. No treatment will be initiated before informed consent has been given. Pre-treatment evaluation will be performed based on the study inclusion and exclusion criteria, including:

1. The inclusion criteria for patients are:
   - Has signed informed consent! (DO NOT RANDOMIZE PATIENT BEFORE INFORMED CONSENT HAS BEEN SIGNED)
   - Is scheduled for treatment of a primary or recurrent NMIBC
   - Is aged 18 years or older

2. The exclusion criteria for patients are:
   - Has or has had tumor(s) in the upper urinary tract
   - Has had previous irradiation of the pelvis
   - 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)
   - Participation in other clinical studies with investigational drugs either concurrently or within the last 30 days
   - 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)
   - Conditions associated with a risk of poor protocol compliance
   - Has had instillation therapy in the six months prior to the screening visit

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 will undergo SPIES and WLI assisted TURB, whereas the patients in the control arm will undergo WLI only assisted TURB.

The following information will asked in the History/Pre-op tabs: Characteristics and History

- Demographics
- Medical history (including previous treatment for NMIBC if tumor is recurrent)
- Urinalysis (including culture)
- Urine cytology
- Upper tract imaging: CT, IVU, MRI or US

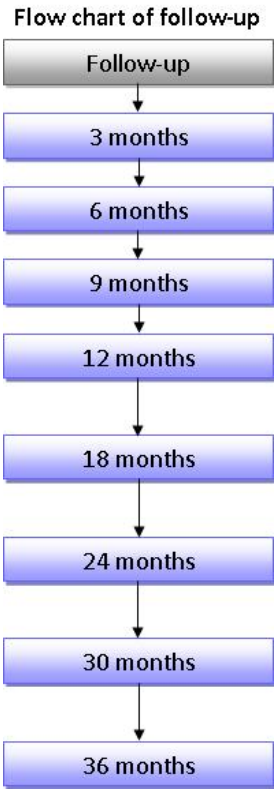
The investigator/research nurse will complete a screening log of all patients who were approached to participate in the trial. This log contains the patients' initials, date of birth and date of visit. If the patient fails to enter the study, the reason(s) for not participating or non-eligibility will be documented.

Treatment with TURB – Visit 2
Following successful completion of the pre-treatment evaluation, patients will continue into the second visit (Intra-op and Post-op tab). This consecutive visit may ideally be combined with Visit 1 and should at the latest take place within 14 days after Visit 1. This visit consists of the surgical procedure.

Peri-operative complications will be recorded when appropriate, up to 30 days of hospitalization. In addition, hospital stay and duration of operation will be recorded. When appropriate, (serious) adverse events ([S]AEs) will be recorded in the adverse events tab.

Re-TUR (4-6 weeks)
Information on re-TUR (between the Post-op period and the first follow-up) will be recorded as well as (serious) adverse events ([S]AEs). [S]AEs will be recorded in the adverse events tab.

Follow-up structure



First follow up – three months after surgery – Visit 3
At three months after surgery, all patients will undergo a routine follow up using WLI cystoscopy. A two-week window will be allowed for the timing of this examination. All visible lesions should be confirmed histologically. Adjuvant treatment will be offered according to the local protocols. When appropriate, information on re-TUR and/or adjuvant treatment will be recorded, as well as adverse events (in the adverse events tab).

Intermediate follow up – 6, 9, 12, 18, 24 and 30 months after surgery – Visit 4 to 9
At the time points specified above, all patients will undergo a follow up using WLI cystoscopy. A four-week window will be allowed for the timing of this examination. Furthermore, the same information will be asked as was asked for the first follow-up.

Last study follow up – three years after surgery – Visit 10
At three years after surgery, all patients will undergo a follow up using WLI cystoscopy. A four-week window will be allowed for the timing of this examination. Furthermore, the same information will be asked as was asked for the first follow-up.

For a more elaborate study procedure see section 3.4 of the protocol.

Entering patients to the DMS
In order to start entering patients in the SPIES RCT (SPIES vs WL RCT) please use the following link http://www.croesoffice.org/DataManagementSystem.aspx in your browser and enter the DMS with your login and password.

If you do not have a username and password, and you would like to participate in one of the current studies, please contact the CROES office: info@croesoffice.org

PLEASE DO READ THE HELP-FILE (Click HELP after login)!