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# AUA VIRTUAL EXPERIENCE



## Safety evaluation of sequential Mitomycin and Bacillus Calmette-Guérin treatment versus Bacillus Calmette-Guérin monotherapy in patients with High risk Non-Muscle Invasive Bladder Cancer (EUDRACT Number 2017- 004540-37): MITOBCG preliminary results

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## Aim

to evaluate efficacy and safety of sequential Mitomycin and Bacillus Calmette-Guérin treatment versus Bacillus Calmette-Guérin monotherapy in patients with High risk Non-Muscle Invasive Bladder Cancer

## Material and Methods

MITO-BCG is an open-label phase 4 study designed to evaluate the efficacy and safety of the sequential MMC and BCG combination treatment in patients with high-risk NMIBC

### Inclusion Criteria

- Patients with high risk non muscle invasive bladder cancer
- High risk of recurrence (EORTC risk score  $\geq 10$ )
- Males
- Signature of Informed Consent
- Ability of consent

### Exclusion Criteria

- Low Risk Non-Muscle Invasive Bladder Cancer
- Muscle Invasive Bladder Cancer
- Concomitant Urothelial Bladder Cancer in the Upper-Urinary Tract
- Previous bladder or prostate surgery
- Prostate or bladder radiotherapy
- Urinary tract infection
- Chronic urinary retention or indwelling catheters
- Neurological patients
- Previous BCG infections
- Previous or current chemotherapy for other kind of cancers
- Patients older than 75
- WHO performance status 3-4
- Residual tumour on re-TURB

### Flow Chart

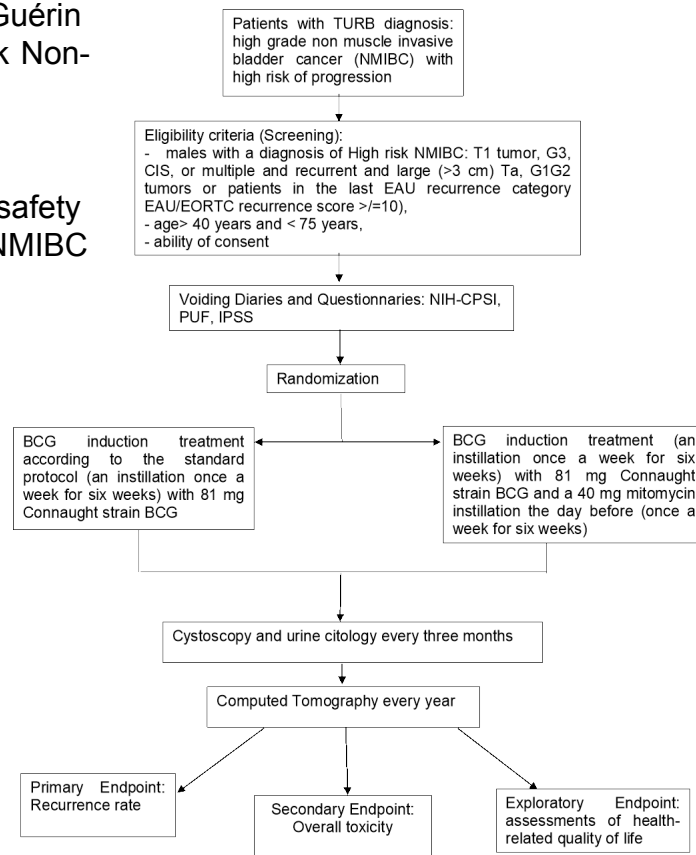




Table 1: Comparison between groups

	Monotherapy BCG Group	Combination Therapy Group	p
Patients	21 (58%)	15 (42%)	
IPSS	9 (IQR 4/11)	11 (IQR 8/15)	0,21
sIPSS	5 (IQR 2/9)	8 (IQR 2/10)	0,27
vIPSS	2 (IQR 1/5)	5 (IQR 1/6)	0,31
NIH-CPSI total	8 (IQR 6/11)	8 (IQR 6/19)	0,13
NIH-CPSI pain	2 (IQR 1/3)	1 (IQR 0/7)	0,12
NIH-CPSI micturition	3 (IQR 1/6)	4 (IQR 1/8)	0,74
NIH-CPSI Qol	3 (IQR 2/4)	5 (IQR 2/6)	0,14
PUF total	15 (IQR 10/21)	15 (IQR 11/21)	0,91
PUF SS	9 (IQR 6/11)	9 (IQR 7/10)	0,89
PUF BS	6 (IQR 5/8)	6 (IQR 5/8)	0,86
AEs	3 (50%)	3 (50%)	0,92
Grade I	2 (67%)	3 (100%)	0,57
Grade II	0	0	
Grade III	1 (33%)	0	0,54
Grade IV	0	0	
Grade V	0	0	



## Conclusions

- Protocol study started on March 2019
- Enrollment will continue till 200 patients are included
- Preliminary results of our experience (MITOBCG study) support that sequential combination therapy with Mytomicin and BCG is a safety treatment in high risk non muscle invasive bladder cancer.

[www.clinicaltrials.gov](http://www.clinicaltrials.gov)

*Protocol Number: NCT03790384*