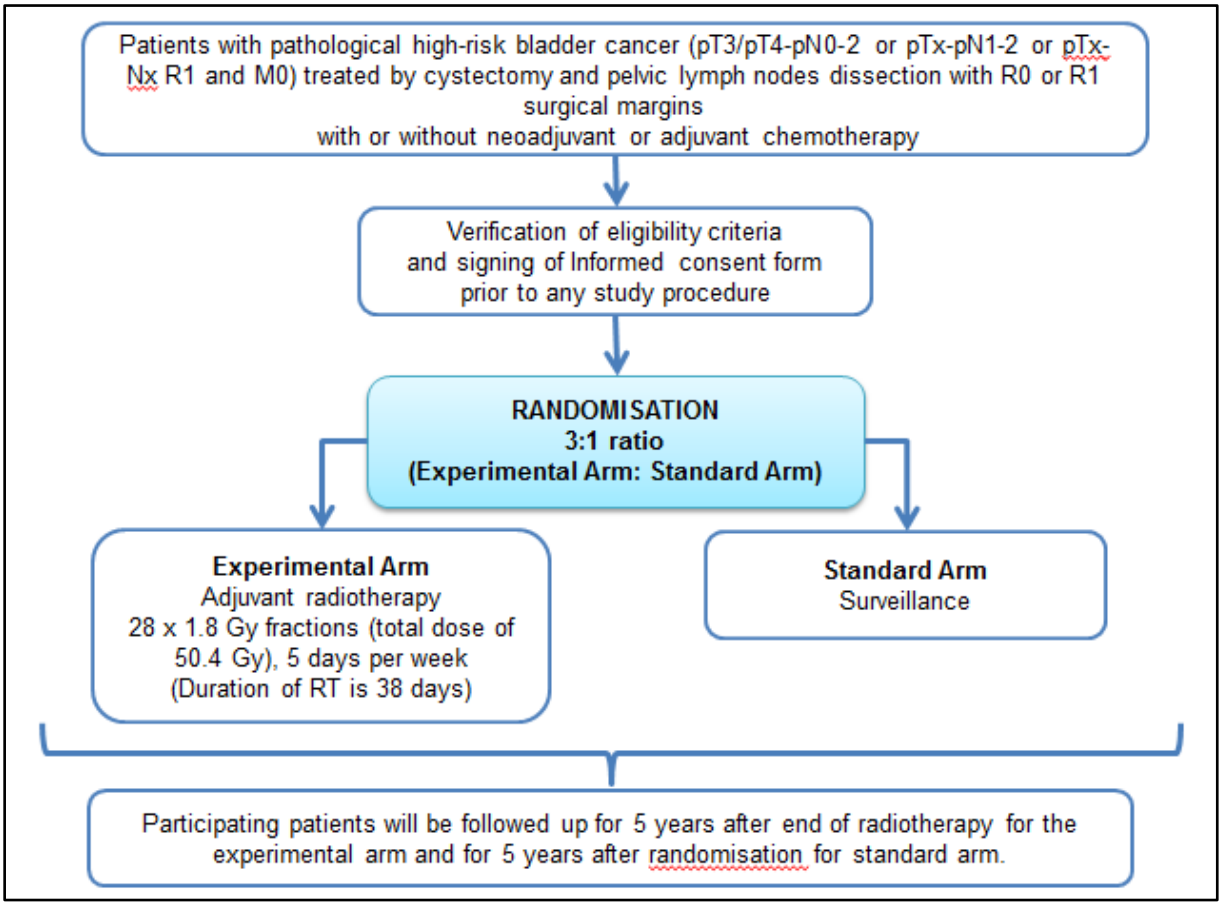
CGFL CENTRE GEORGES FRANÇOIS LECLERC Ensemble, dépassons le cancer	**CRITERES DE SELECTION** **ETUDE GETUG AFU 30**	Identité patient (coller étiquette patient)
Version 1.0 du 24-10-2021	Investigateur en charge du patient : …….. PI : **Dr Etienne MARTIN** Mail :emartin@cgfl.fr *A contacter pour adresser/inclure patient externe au CGFL*	Arc : **Patricia LECERF** Poste : 8084

« GETUG-AFU30 »

Adjuvant radiotherapy in patients with pathological high-risk bladder cancer: A randomised multicentre phase II study: Bladder-ART study



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VALIDATION DES CRITERES DE SELECTION

Critères d'inclusion :

Patients with histologically-confirmed muscle-invasive bladder cancer, either with pure urothelial carcinomas, or dominant urothelial carcinomas (>50%) combined with other histological variants including: micropapillary, epidermoid, or adenocarcinomas, are eligible. Patients with small cell variants, pure adenocarcinomas, or pure epidermoid carcinomas are not eligible	□ oui □ non
Patients with radical cystectomy and pelvic lymph nodes dissection with no microscopic residual disease (R0 and R1). Note that only R1 patients without urinary diversion as orthotropic neo-bladder replacement are eligible for the study, to limit cystectomy bed radiation induced toxicities.	□ oui □ non
Patients with tumours of TNM staging: pN0-2, M0 by imagery, and pT3a, pT3b, pT4a, and pT4b, as well as, pTX-pN1-2 and pTx-pNx-R1 are eligible.	□ oui □ non
Patients having received neo-adjuvant or adjuvant chemotherapy treatment are eligible. Randomisation is allowed only if AE due to chemotherapy are ≤ grade 2 at randomisation.	□ oui □ non
Patients ≥18 years old.	□ oui □ non
ECOG performance status ≤2.	□ oui □ non
Absolute neutrophil count (ANC) ≥1500 cells/mm3	□ oui □ non
Platelets ≥100000 cells/mm3	□ oui □ non
Haemoglobin ≥8 g/dL (Note: following a blood transfusion or another intervention if required).	□ oui □ non

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Adequate hepatic function: AST (SGOT) and ALT (SGPT) ≤2.5 x ULN or ≤3.5 x ULN in the case of concurrent disease with known etiology and for which a corrective treatment is possible.	□ oui □ non
Adequate renal function: clearance >30 mL/min (MDRD).	□ oui □ non
Patients having provided written informed consent prior to any study-related procedures	□ oui □ non
Patients affiliated to the social security scheme.	□ oui □ non
Patients willing and able to comply with the scheduled visits, treatment plan, laboratory tests, and other study procedures indicated in the protocol.	□ oui □ non

Critères de non inclusion :

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Patients with **R1** resection **and** with **orthotropic neo-bladder reconstruction as urinary diversion** are not eligible.	□ oui □ non
Patients with clinical or radiological evidence of metastases or N3 staged bladder cancer are not eligible.	□ oui □ non
Prior invasive solid tumours or haematological malignancies unless disease free for a minimum of 3 years prior to randomisation, except: □ *in situ* epithelioma of the cervix, Skin basal cell carcinoma □ or prostate cancer: incidentally discovered during cystoprostatetectomy and pelvic lymph node dissection and with a good prognosis (T stage <pT3b and/or Gleason <8 and pN- and/or post-operative PSA <0.1 ng/mL)	□ oui □ non

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Prior pelvic radiotherapy.	□ oui □ non
Patients with active inflammatory bowel disease.	□ oui □ non
Patients who required surgical treatment for bowel obstruction before bladder cancer diagnosis or after cystectomy.	□ oui □ non
Prior chemotherapy for other malignant diseases within the previous 5 years, except for neoadjuvant pre-cystectomy chemotherapy or adjuvant chemotherapy which are permitted	□ oui □ non
Patients with the following severe acute co-morbidity are not eligible: Unstable angina or congestive heart failure that required hospitalization in the 6 months before randomisation. Acute bacterial or fungal infection requiring intravenous antibiotics at randomisation. Chronic obstructive pulmonary disease exacerbation or other respiratory illness requiring hospitalization or precluding study therapy at the time of randomisation. Severe hepatic disease: Child-Pugh Class B or C hepatic disease. Known acquired immune deficiency syndrome (AIDS); the study treatment could impact blood count. Unstable angina or congestive heart failure that required hospitalization in the 6 months before randomisation. Transmural myocardial infarction in the 6 months prior to randomisation.	□ oui □ non
Patients with any other disease or illness which requires hospitalization or is incompatible with the study treatment are not eligible.	□ oui □ non

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Patients unable to comply with study obligations for geographic, social, or physical reasons, or who are unable to understand the purpose and procedures of the study.	□ oui □ non
Patients enrolled in another therapeutic study within 30 days prior of randomisation.	□ oui □ non
Person deprived of their liberty or under protective custody or guardianship.	□ oui □ non

Date : _____ Signature de l'investigateur : _____