Project title

Urine methylation pattern as a tool for early diagnosis, non-invasive monitoring and estimation of recurrence risk in bladder cancer

Principal Investigator

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Involved Centers

IFO-IRE, Rome (coordinator); CRO, Aviano; ISPRO, Florence.

Study design

Multicentric, observational, non-interventional, prospective study with an estimated duration of 18 months. Planned activities will be focussed at: (a) evaluating performances of commercial assays (e.g., BladderCARE, Bladder EpiCheck) in a real-world clinical scenario; (b) developing and validating novel approaches based on next generation sequencing or whole genome sequencing, comparing them to the above tests; (c) scoring the risk of recurrence and/or clinical outcome based on methylation patterns.

Background

Bladder cancer is among the 10 most commonly cancers diagnosed in human. In 70% of cases, the outcome after transurethral resection appeared as favourable (10-year survival = 80%) but recurrence rates are very high (1). Therefore, timely and accurate clinical surveillance is mandatory. To date, no active, surveillance programs have been strictly codified by the Italian NHS. Published guidelines recommend the use of cystoscopy, imaging or urinary cytology (1, 2) but these methods are invasive, not sensitive enough or cancer-specific. Therefore, a strong interest in assessing novel predictive/prognostic tools is emerged. Recently, non-invasive laboratory tests based on urine have been developed enabling to uncover tumor presence and following its evolution over time. Although largely not in clinical practice, published results have demonstrated their applicability and impact. In this framework, our Institute intends to promote a study aiming at investigating whether the analysis of methylation patterns via liquid biopsy (urine) may improve the identification of patients bearing bladder cancer or with poor clinical outcome. The study would like to standardize a workflow potentially exportable to the NHS, demonstrating its advantages in identifying cancer patients, predicting clinical outcome and offering non-invasive way for serial monitoring of bladder cancer.

Patient cohort

The study will investigate 2 populations, the first represented by patients affected by bladder cancer (n=50) of non-muscle infiltrating or muscle infiltrating histology, while the second comprising healthy subjects (n=100) as controls. Urine samples will be serially collected from both groups in the occasion of clinical visits.

Bibliografia di riferimento

1. Compérat E. et al. Current best practice for bladder cancer: a narrative review of diagnostics and treatments. Lancet (London, England). 2022;400(10364):1712-21.
2. Babjuk M et al. European Association of Urology Guidelines on Non-muscle-invasive Bladder Cancer (Ta, T1, and Carcinoma in Situ). European Urology. 2022;81(1):75-94.

Rome, March 25th 2024

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Ministero della Salute

Funded by the European Union - Next Generation EU - and Ministero della Salute PNRR PNC-E3-2022-23683266 PNC-HLS-DA, INNOVA"
Finanziato da European Union - Next Generation EU - e Ministero della Salute PNRR PNC-E3-2022-23683266 PNC-HLS-DA, INNOVA"