Method for predicting the therapeutic response to BCG anti-cancer treatment in bladder cancer.

The research group led by Dr Mar Valés-Gómez at the National Center for Biotechnology (CNB-CSIC), together with Scientists from the Hospital Infanta Sofía (Madrid) and the National Institute for Biological Standards and Control (NIBSC) from UK, has developed a new method for predicting and monitoring the therapeutic response of bladder cancer patients to anti-cancer immunotherapy based on the intravesical administration of *Bacille Calmette-Guérin (BCG),* an attenuated strain of *Mycobacterium bovis*. Companies interested in a patent license are being sought

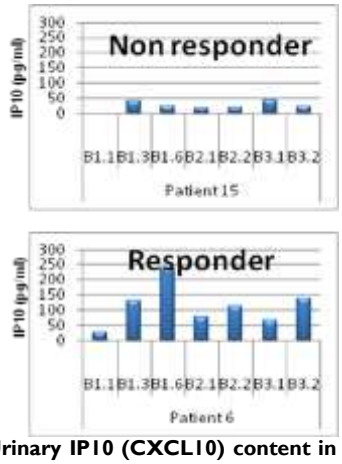
An offer for Patent license

Patients that positively respond to BCG treatment present a progressive increase in urinary IP10 expression levels.

Intravesical instillations of BCG are the standard therapy for the treatment of high grade superficial bladder cancer, also called non-muscle invasive bladder cancer (NMIBC), accounting for about 75% of newly diagnosed cases. BCG is used as a primary therapy for carcinoma *in situ* and as an adjuvant for papillary tumors after trans-urethral resection.

Stimulation of the immune system by intravesical instillations of BCG has been known to be an effective treatment for bladder cancer for almost four decades. Patients receive weekly instillations of BCG during 6 weeks, followed by a 3 month rest period. The treatment continues for 3 years, with a recall therapy of 2-3 weekly instillations separated by 3 months rest periods.

Around 70% of the patients remain free of relapse during 5 years after BCG treatment, however around 30% of the patients do not respond to the treatment. A non-invasive method for an early prediction of non-responders to BCG before tumor recurrence appears is needed to improve their chances of survival.



Urinary IP10 (CXCL10) content in BCG-treated bladder cancer patients. Samples were collected before receiving the instillations in weeks 1, 3 and 6 (B1.1, B1.3, B1.6) of the first cycle and the two recall instillations of the next cycles (B2.1, B2.2, B3.1, B3.2). IP10 in pg/ml is measured by Luminex, of a responder and a non-responder patient.

Main innovations and advantages

- The method is simpler, more reliable, and less invasive than other methods for predicting/monitoring the therapeutic response to BCG.

- The method is useful for predicting bladder cancer recurrence following BCG treatment before new tumor cells are released to the urine, allowing selection of patients for alternative anti-cancer therapies.

- The urine is collected from the subject at initial point (before the first BCG instillation) and 7 days after BCG administration during the first weeks of treatment, in order to detect progressive increase in IP10.

- The urine protein levels of IP10 one week after BCG treatment are > 50 pg/ml in patients with a positive immune response.

- The method can be applied to biological tissues and/or fluids collected from a subject such as urine.

Patent Status

Spanish Priority Patent has been filed

For more information, please contact:

Ana Sanz Herrero
Technology Transfer Manager
Centro Nacional de Biotecnología (CNB-CSIC)
Tel: 91 585 4306
E-mail: asanz@cnb.csic.es

MINISTERIO DE ECONOMÍA Y COMPETITIVIDAD
CSIC
Consejo Superior de Investigaciones Científicas