Kit for the prediction of the clinical response to an anti-colorectal cancer therapy

Kit for predicting the clinical response of a patient suffering from colorectal cancer to a neoadjuvant antitumour therapy, involving detection of the expression levels of a genomic fingerprint composed of six specific genes.

Description and essential characteristics

Kit for predicting the clinical response to a neoadjuvant antitumour therapy in a patient diagnosed with colorectal cancer, which is based on a method comprised of the following steps:

(i) Determining the expression levels of six specific genes in a tumour tissue sample from the patient prior to administration of the therapy;
(ii) calculating a predictive factor based on the expression levels of the aforementioned genes; and
(iii) comparing the value of the predictive factor obtained in step (ii) with a reference value.

The predictive factor is calculated by summing the expression levels of the genes, optionally corrected using a coefficient for each gene.

The reference value is calculated from the expression values of the six genes that constitute the genomic fingerprint in a sample population composed of responders and non-responders to an antitumour therapy. Specifically, a higher degree of prediction reproducibility, reliability and sensitivity can be achieved when calculating the reference value by averaging the values obtained from the sample population of patients who do not respond to an antitumour therapy.

The kit, based on the results of the comparison between the predictive factor value and the reference value, enables the user to predict whether the patient will have a better or worse response to an anticancer therapy. A deviation in the predictive factor value with respect to the reference value is indicative of a poorer clinical response to the antitumour therapy, or denotes that the patient has a low likelihood of responding to an antitumour therapy.

Competitive advantages

This new kit has predictive value of response to treatment in colorectal cancer and enables a significant discrimination between the various grades of pathological response—classified as non-response, good response and full-response—based on the tumour regression grade value. Currently, there are no commercially available kits to predict neoadjuvant treatment response in rectal cancer.

The prediction of response to treatment makes it possible to develop appropriate treatments and to act more or less aggressively.

The non-response to an antitumour therapy is predicted with a high sensitivity of 80%. This prediction is of great value, as if there is a very low likelihood of benefit, the usual protocol of preoperative treatment should be abandoned and the patient should be operated on directly. This would prevent unnecessary delays in local treatment, which increase the risk in these patients of developing distant metastasis and local complications, such as intestinal obstruction. Unnecessary exposure of the patient to chemoradiotherapy toxicity would also be avoided.

Type of collaboration sought

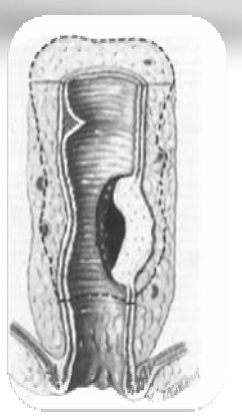
Cooperation is sought with any Party interested in partnering, licensing or investing in the technology, whether it be an investor to fund the project, a partner interested in getting involved in any of the various phases until its placement on the market, a patent licensee, etc. Organisations potentially interested in this technology are those devoted to the manufacture, commercialisation and/or distribution of disease diagnosis kits; as well as universities, hospitals, research centres and all types of institutions engaged in cancer diagnosis and treatment research.

Current stage of development

In vitro studies on more than 50 human samples were carried out with promising results.

Current state of intellectual property

Spanish patent P201130863, granted in February 2014.
International patent application PCT/ES2012/070379.



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Technology Offer from the Foundation for Biomedical Research of La Paz University Hospital