Test for predicting the prognosis of a patient with colorectal cancer

The COLOLIPID test predicts the prognosis of a patient diagnosed with colorectal cancer (CRC) and assists in the selection of a suitable treatment. The test is based on the detection of the expression levels of a biomarker, ColoLipidGene, which is composed of four genes.

Description and essential characteristics

COLOLIPID is a diagnostic test that predicts the prognosis, in terms of the risk of relapse, of a patient who is newly diagnosed with stage II colorectal cancer. The test is also able to identify whether that patient will benefit or not from chemotherapy treatment after the primary surgery to remove the tumour. The test works by examining the tumour tissue at a molecular level to provide information about the individual biology of that specific tumour.

COLOLIPID is based on the evaluation of a biomarker called ColoLipidGene to determine the likelihood that the cancer cells will spread—or metastasize—within three years after diagnosis. COLOLIPID carries out a combined analysis of the expression levels of four genes within the colorectal tumour that are involved in cell energy metabolism. The test reflects the energetic capacity of the tumour cells, thus revealing the potential aggressiveness of the tumour. In addition, the four genes that constitute the biomarker are metabolic enzymes with a high affinity for specific drugs ("druggable" enzymes), which suggests these molecules could be relevant targets for anticancer therapy.

The COLOLIPID test identifies a patient´s risk of distant, local or regional relapse. The combination of the COLOLIPID test with the patient´s clinical and pathological factors further personalises the estimate of a patient´s risk of relapse and helps both the patient and the clinician to decide on pursuing additional treatment (such as chemotherapy) after the surgery to remove the tumour.

Competitive advantages

The primary advantages of the COLOLIPID test versus its main competitors (Coloprint and Oncotype) are the following:

1. Higher predictive accuracy and reliability (comparative studies versus competitors have been carried out).
2. Simplicity (the biomarker is composed of only four genes).
3. The four genes that make up the biomarker have prognostic value separately, so an experimental mistake in a determination would not have great consequences in the global test.
4. The four genes of the biomarker are in the same biological process, which could be regarded as "metabolic activation", thus indicating that the test could also be useful for other types of tumours.
5. The samples used in the studies were formalin-fixed paraffin-embedded biopsies (FFPE biopsies) exclusively from patients with stage II colon cancer.

Type of collaboration sought

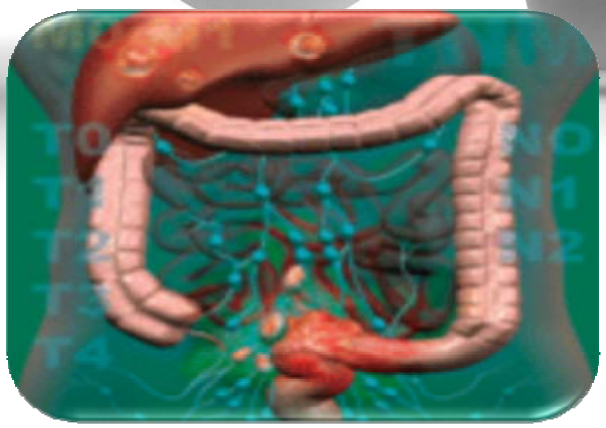
Cooperation is sought with any Party interested in partnering, licensing or investing in the technology, whether it be an investor to fund the project, a partner interested in getting involved in any of the various phases until its placement on the market, a patent licensee, etc. Among the organisations potentially interested in this technology would be 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 addition to the trials carried out in the design phase (77 patients with stage II colon cancer), the value of this test was further confirmed in a validation set of 119 patients (La Paz Hospital in Madrid) and followed a second validation in an additional set of 120 patients from various hospitals (Barcelona y Valencia).

Current state of intellectual property

Spanish patent P201231918, granted in April 2015.
International patent application PCT/ES2013/070864.



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