An innovative evidence-based laboratory medicine (EBLM) test to help doctors in the basic assessment of main non-malignant, highly prevalent, morbid, cancer-precursor, and deadly diseases

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Background-aim

To develop a novel non-invasive, evidence-based laboratory medicine (EBLM) test to assist doctors in assessing the main body functions, systems and metabolisms, and to evaluate its accuracy in detecting the main non-malignant, highly prevalent, morbid, cancer-precursor, and deadly diseases.

Materials & Methods

This study is part of a previous one already published at the European Society for Medical Oncology (ESMO) Congress 2024, which is focused on the accuracy evaluation of a novel non-invasive test for Multi-Cancer Early Detection (MCED). To develop the algorithm, several combinations of analytes were analyzed to identify the most significant groupings related to the main body functions, systems and metabolisms. The algorithm's efficiency was then enhanced using serial and parallel approximation techniques. Its performance was trained with a dataset of 185,882 patients. The validation of the algorithmic test was performed through a randomized controlled trial (RCT) with a sample size of 152 patients. Their blood samples were tested by Laboratorio Echevarne (Spain), using their hematology and biochemistry techniques.

Results

For the RCT, the sensitivity achieved was 1.00 and the specificity was 1.00. Additionally, the area under the receiver operating characteristic (AUROC) curve, the positive predictive value (PPV), and the negative predictive value (NPV), were 1.00, 1.00, and 1.00, respectively. This indicates a strong correlation between the algorithm outcomes and the high likelihood of having a non-malignant, highly prevalent, morbid, cancer-precursor, and deadly disease.

Conclusions

This innovative non-invasive blood-based biomarker algorithm holds promise in helping doctors in providing timely and accurate basic assessment of the main non-malignant, highly prevalent, morbid, cancer-precursor, and deadly diseases —even in early stages—, as well as reduce medical errors or misdiagnoses. These results advocate further exploration, prompting our intention to conduct a clinical study involving 26,000 participants to enhance our findings and inform clinical practice.