

DIAGNOSTIC PROCEDURE TO IDENTIFY PATIENTS WITH MINIMAL HEPATIC ENCEPHALOPATHY

DESCRIPTION OF THE INVENTION

Researchers from two Valencian biomedical research centers (Centro de Investigación Príncipe Felipe and INCLIVA) have identified a peripheral biomarker which allows diagnosing the presence of Minimal Hepatic Encephalopathy (MHE) in patients with liver cirrhosis (more than 2,000,000 in the European Union). This biomarker could provide a significant improvement in MHE diagnosis standard and, consequently, in the quality of life and life span of patients

Hepatic Encephalopathy (HE) is a complex neuropsychiatric syndrome present in patients with liver diseases that leads to alterations in personality, sleep-waking cycle, cognitive function, motor activity and coordination and level of consciousness and may lead to coma and death.

Between 33-50% of cirrhotic patients without clinical symptoms of HE show chronic Minimal Hepatic Encephalopathy (MHE) (more than 2,000,000 in the European Union), with mild cognitive impairment and motor alterations, which can be unveiled using neuropsychometric or neurophysiological tests.

MHE increases the probability of suffering driving, home and working accidents, predicts the

appearance of clinical HE and reduces the quality of life and life span. MHE is therefore an important clinical, social and economical problem.

Early diagnosis and treatment of MHE would improve the quality of life and life span of the patients and prevent the progression of the neurological impairment.

Currently, the gold standard for diagnosis of MHE in patients is the Psychometric Hepatic Encephalopathy Score (PHES), a battery of 5 psychometric tests. However, the PHES results must be corrected by age and educational level, is time-consuming and is not routinely performed in most Hospitals services. As a consequence, MHE is not routinely diagnosed in most clinical settings due to lack of simple procedures and most patients with MHE remain undiagnosed and untreated.

This new peripheral biomarker (metabolite) allows diagnosing the presence of Minimal Hepatic Encephalopathy in patients with liver cirrhosis and can be measured in blood, overcoming the limitations of current standard.

BUSINESS SECTORS OF APPLICATION

Pharmaceutical and biotech companies focused on diagnostics and/or hepatic and liver diseases:

TECHNICAL ADVANTAGES & BUSINESS PROFITS

The levels of this metabolite have shown very good diagnostic accuracy:

- Sensitivity: proportion of patients with MHE which are correctly identified: 89%
- Specificity: proportion of patients without MHE which are correctly identified: 93%
- Positive predictive value: proportion of patients with positive test results who are correctly diagnosed: 91%
- Negative predictive value: proportion of patients with negative test results who are correctly diagnosed: 91%
- The ROC curve analysis for the diagnosis of MHE showed an area-under the curve (AUC) value of 0.96 (95% CI: 0.93-0.99)

DEVELOPMENT OF THE TECHNOLOGY

The method has already been validated with patients.

INDUSTRIAL PROPERTY RIGHTS

A European patent application has been filed (application nr. EP11806343.7).

SOUGHT COLLABORATION

Licensing/collaboration agreement in order to develop a diagnostic kit (e.g. ELISA-based) and its commercialization.

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