ciber-bbn

Method for diagnosis, prognosis and monitoring of Alzheimer disease using metabolomic techniques

Market sector:
Diagnostics, Neurology

Type of opportunity:
Licensing and/ or co-development

Patient need addressed:
Alzheimer's disease

Competitive advantages:
Non-invasive and economic in vitro analysis. High sensitivity (94%) and specificity (88%). Suitable for clinical use. Reliable method based on plurality of metabolites. Individualized quantification of metabolites is not necessary.

Scope of the problem

Alzheimer's disease (AD) is a neurodegenerative disorder, and is the most common cause of dementia. AD is thought to begin 20 years or more before symptoms arise, with changes in the elderly brain that are unnoticeable to the person affected. Only after years of brain damage do individuals experience overt symptoms, and as the disease progresses, the individual is not able to carry out basic daily functions. AD is ultimately fatal. Understanding the mechanisms associated with AD is, therefore, especially important for the identification of diagnostic, and prognostic biomarkers, and therapeutic approaches as well as disease-modifying.

Metabolomics is a powerful tool that allows obtaining an accurate biochemical profile of the organism, both in a pathological situation and in a health or control situation. Based on this premise, AD diagnosis and monitoring methods have been described, as well as the risk of suffering from the disease, developed from metabolomic studies of tissues and fluids, such as blood serum, which have allowed the identification of new biomarkers associated with the disease.

However, none of these methods has been replicated in different and broad cohorts, so new methods and tools, alternative or improved, based on the analysis of the metabolomic profiles of individuals, must be developed, which allow the early identification of AD and discrimination between this disease and other dementias with high sensitivity and specificity. This would facilitate an early therapeutic intervention necessary to avoid, slow down or delay the onset of the disease.

Our innovation:

- Innovative *in vitro* method for diagnosis, prognosis and monitoring of Alzheimer's disease (AD) using the metabolic profile in serum of an individual.
- The new method includes a sample preparation and NMR acquisition protocol, a mathematical algorithm and a suitable software for data processing.
- The mathematical model applies not only the biomarkers identified as relevant, but the complete metabolomic profile of the sample.
- The method has both high sensitivity and specificity which are suitable for clinical use.
- Reproducible data acquisition within the same patient as well as with different individuals.
- The method allows the early diagnosis of the disease and monitoring the evolution of patients with suspected AD.
- Potentially this invention might be useful for differential diagnosis between AD and other dementias.
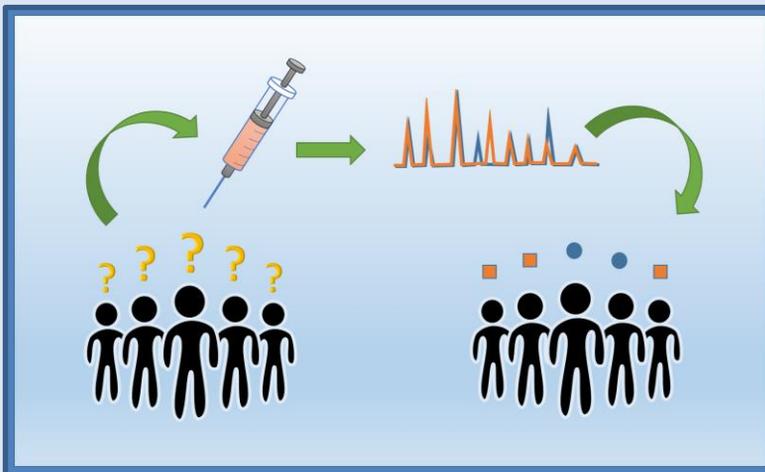
Market size/ opportunity: "In 2015 the number of people with dementia was approx. 10.5 million in Europe, and is predicted to increase to 13.4 million by 2030 and to 18.7 million by 2050. AD accounts for 60 to 80 % of dementia cases" (AAL, Alzheimer Europe, 2019).
"In USA total annual payments for health care, long-term care and hospice care for people with Alzheimer's or other dementias are projected to increase from $305 billion in 2020 to more than $1.1 trillion in 2050. In 2019, caregivers of people with Alzheimer's or other dementias provided an estimated 18.6 billion hours of informal (that is, unpaid) assistance, a contribution to the nation valued at $244 billion" (Alzheimer Association, 2020).

Intellectual property
(Priority date: March 23, 2020)
International patent application, PCT (March 23, 2021)

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