Commercialization of a serum diagnostic for detection of Alzheimers Disease

https://neurodegenerationresearch.eu/survey/commercialization-of-a-serum-diagnostic-for-detection-of-alzheimers-disease/

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Institution

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Contact information of lead PI
Country

USA

Title of project or programme

Commercialization of a serum diagnostic for detection of Alzheimers Disease

Source of funding information

NIH (NIA)

Total sum awarded (Euro)

€ 1,050,373.39

Start date of award

15/08/2015

Total duration of award in years

2

The project/programme is most relevant to:

Alzheimer's disease & other dementias

Keywords

Acquired Cognitive Impairment... Aging... Alzheimer's Disease... Alzheimer's Disease including Alzheimer's Disease Related Dementias (AD/ADRD)... Brain Disorders... Dementia... Diagnostic Radiology... Immune System... Neurodegenerative... Neurosciences... Prevention... Translational Research

Research Abstract

? DESCRIPTION (provided by applicant): Commercialization of a blood diagnostic for early detection of Alzheimer's Disease The goal of this research is to demonstrate proof of concept in being able to utilize a disease marker in the blood to develop a diagnostic 'test' for the early detection and staging of Alzheimer's disease (AD). AD is a chronic neurodegenerative disease for which there is no cure. By 2050 the incidence of AD is expected to approach 1 million/year with a total estimated prevalence of 11-16 million at a cost of $172B. It is generally recognized that effective treatments for slowing or halting disease progression will have to be administered very early following onset of the disease. Identification of a robust blood test for identifying ealy AD will be essential as a population screening tool for identifying at-risk individuals for therapeutic interventions aimed at both halting disease progression and/or modifying the rate of cognitive decline. The sensitivity of cerebrospinal fluid biomarkers and brain imaging technologies to stage AD disease progression are improving, but fall short of being used as regular screening techniques for various reasons. At present there are no accepted biomarkers in blood that are clinically useful to identify individuals for developing AD. Recent discoveries have demonstrated that autoantibodies circulate in blood that have their antigen binding sites 'masked' such that they do not react with self-antigens. A novel class of masked autoantibodies against phospholipids (aPL) universally present in blood have been demonstrated to be present using proprietary technology to oxidatively 'unmask' autoantibody aPL reactivity. These redox-reactive autoantibodies (R-RAA) in blood samples can be quantitatively measured using standard clinical 'antigen down' ELISA assay formats, and form the basis of the diagnostic test. Studies have been completed that demonstrate that the level of R-RAA aPL are significantly elevated in blood samples from subjects with amnestic Mild Cognitively Impaired (MCI) compared to blood samples taken from cognitively normal age-matched healthy subjects. NIH SBIR funding will be used to enable testing of blood samples taken from a relatively large number of subjects over a period of time (longitudinal studies). The R-RAA aPL data from these studies will allow comparison of blood biomarker levels taken when subjects are asymptomatic and followed as the earliest signs of cognitive impairment become apparent. The studies will determine if the biomarker can be used for identifying at-risk asymptomatic individuals early in disease progression. A successful outcome of these studies will determine if clinical validation and commercialization of the R-RAA aPL diagnostic test is warranted for use as a screening tool to meet this very challenging unmet medical need.

Lay Summary
PUBLIC HEALTH RELEVANCE: Alzheimer's dementia is an incurable chronic brain-wasting disease primarily afflicting the elderly, expected to reach 16 million in the US alone by 2050, at cost of approximately $172 billion. Treating the disease effectively in the future will require ver early diagnosis using a blood test. A proprietary technology that promises to meets these requirements is currently under development by the applicant's Company using NIH SBIR funding to accelerate product development. 1

Further information available at:

Types:
Investments > €500k

Member States:
United States of America

Diseases:

Alzheimer's disease & other dementias

Years:
2016

Database Categories:
N/A

Database Tags:
N/A