Regulatory Approval of the OLFACT Test Battery

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Country

USA

Title of project or programme

Regulatory Approval of the OLFACT Test Battery

Source of funding information

NIH (NIA)

Total sum awarded (Euro)

€ 1,111,456.88

Start date of award

30/09/2015

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... Clinical Research... Clinical Research - Extramural... Dementia... Neurodegenerative... Neurosciences

Research Abstract

? DESCRIPTION (provided by applicant): Although there are numerous scientific studies in the

literature that show impairments in olfaction often occur early in the onset of Alzheimer's Disease (AD), there is still concern pertaining to the specificity of measures of olfactory dysfunction when used as a predictor of AD. For this and other reasons, there is no test based upon measures of olfactory function that has been cleared by the FDA for use as a screen for the disease. Consequently, the major goal of this application is comprised of two different but closely related components: 1) validating the OLFACT(tm) Test Battery (TB) as a sensitive, early predictor of AD; and 2) gaining FDA clearance of the OLFACT(tm) TB for use as a screening test in the assessment of AD. To achieve this goal two specific projects are proposed. The first is to demonstrate that impairments in olfactory function predict onset of AD. To accomplish this, in Phase I an automated test of olfactory function, the OLFACT(tm) TB will be developed and used to measure olfactory function in participants of the Rush University Medical Center Memory and Aging Project, a longitudinal cohort in which over 1000 participants are being evaluated for the development of MCI and AD. Participants in these studies are extensively evaluated on an annual basis with batteries of neuropsychological tests, neurological exams, and clinical assessments. Using logistic regression, this comprehensive data set will be used in conjunction with neuropathologic data-the “”gold standard”” for diagnosing AD–to be collected during Phase II to determine the predictive utility of olfactory function as a screening test for AD. The exhaustive nature of this data set will allow other causes of olfactory dysfunction as well as other cause of dementia to be documented and controlled for. Also in Phase II, in a second project at Massachusetts General Hospital, approximately 200 subjects will be recruited who have already been extensively evaluated for AD and, in addition, many have also received both volumetric MRI's and amyloid PET. These subjects will be administered the OLFACT(tm) TB during the course of the project to evaluate how well these other biomarkers compare to measures of olfactory function as a predictor of AD. These combined data sets will form the basis of the second component– a Premarket Approval (PMA) application to the FDA to obtain clearance for the OLFACT(tm) TB as a screening test for AD. The availability of a FDA-cleared test which was valid, noninvasive, inexpensive and an early predictor of AD would be of immense value, not only in the diagnosis of AD in preclinical stages, but also as a way to reduce costs in the recruitment of affected individuals for clinical trials. The test could also prove to e useful in the assessment of the efficacy of potential drug therapies or other therapeutic interventions when measured over time.

Lay Summary

PUBLIC HEALTH RELEVANCE: Alzheimer's disease (AD) is the leading cause of dementia in old age, with 4 to 5 million Americans currently affected, and sharp increases in those numbers are expected by mid-century with the aging of the U.S. population. Impairments in the sense of smell are one of the earliest indicators associated with the development of AD. This proposal will measure olfactory function in two longitudinal studies of AD in order to 1) establish the relationship between loss of sense of smell and AD; 2) determine the relationship between measures of olfactory functions and other biomarkers; and 3) seek FDA clearance of the OLFACT(tm) Test Battery for use as a screening test in the assessment of AD. This would be the first olfactory test cleared by the FDA for this purpose and would provide both clinicians and researchers a powerful tool in the fight against this disease.

Further information available at:

Types:

Investments > €500k

Member States:
United States of America

Diseases:
Alzheimer's disease & other dementias

Years:
2016

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