


Alzheimer's & Parkinson's Diseases
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Presenting auhtor

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ADDIA Chronobiology Study and Proof-of-Performance Study to Validate Blood-Based Biomarkers for the Diagnostic of early Alzheimer's Disease (AD)

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ABSTRACT TEXT

Abstract body

There is an unmet need for an accurate, non-invasive biomarker test for the diagnosis of early Alzheimer's disease (AD). The objectives of the ADDIA program are the analytical validation and the proof-of-performance of a) two cellular biomarkers, β -amyloid and protein kinase C (PKC), using fluorescent probes and b) circulating biomarker candidates, including mRNA, miRNA, lncRNA signatures, protein panels, for AD diagnostic purposes.

Methods: The ADDIA chronobiology study is a monocentric study recruiting 12 patients with mild-to-moderate AD and 12 healthy control subjects; the ADDIA Proof-of-Performance (PoP) study is a multicentric study recruiting 800 subjects into 3 groups: AD patient group (200 early AD and 200 late AD), a group of 200 patients with non-AD dementia (NAD) and 200 healthy controls. During the screening period, neurocognitive assessment, brain MRI data in all subjects, and the CSF biomarker data in AD and NAD groups are collected. During the visit(s), samples including blood and its components are obtained.

Results: The results of the chronobiology study on diurnal impact on biomarkers will be presented. The ADDIA PoP study is ongoing and will provide the first large data sets on the performance of the tested biomarkers, and their correlation to neurocognitive, imaging scores or CSF biomarkers. The most accurate biomarker combination will be selected for use as Research-Use-Only test and for submission to regulatory agencies for approval as an in-vitro diagnostic (IVD) tool for the context of use of diagnostic of AD, differential diagnostic. The other future clinical applications are for prognostic or theragnostic purposes.

Keywords

Early Alzheimer

Blood biomarker-based tests

In-Vitro-Diagnostic

Diagnosis

Differential Diagnosis