Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

Elecsys® Amyloid Plasma Panel (EAPP) Clinical Performance Study

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Elecsys® Amyloid Plasma Panel (EAPP) Clinical Performance Study

1. Study Information	
Name of the study	A multicenter, prospective, non-interventional study to determine the cutoff and clinical performance of the Elecsys® Amyloid Plasma Panel and its component assays
Study sponsor	Roche Diagnostics International Ltd
Disease	Alzheimer's disease
Phase	Not applicable - clinical performance study for in vitro diagnostic medical devices (IVDR)

2. Information about the intervention that will be tested in the study	
Name of the intervention	Elecsys® Amyloid Plasma Panel (EAPP). It is an innovative blood test that aims to facilitate the earlier diagnosis of Alzheimer's disease.
Is the intervention already on the market for another medical condition?	No
Will all participants receive the same intervention?	All participants will be tested with EAPP.

3. Information about participating in the study	
What are the researchers trying to find out?	• The purpose of the cutoff establish study part is to derive the score formula (including score parameters) and to calculate a cut-off for the EAPP which maximizes the clinical performance in the intended use population • The purpose of the pivotal clinical study part is to demonstrate the clinical performance of the EAPP in terms of its ability to rule out people in the intended use population, who are most likely to be amyloid negative.
How long will the study last?	• Approximately 1 year

	• Followed by a 3 month follow up period
What your involvement will entail?	First, participants will be asked to undergo a screening visit consisting of questionnaires to access memory, cognition and behaviour (i.e. MMSE, QDRS). Eligible subjects will then be invited for further visits and will be asked to: • Complete some laboratory tests such as blood collection • Do a clinical interview • Complete a test that will assess memory, orientation, judgment and problem solving, personal care and community affairs (this is a test called CDR) • Undergo brain scan (amyloid PET scan and brain MRI) and/or CSF examination (spinal tap).

4. Who can participate in this study?	
Who can participate in the study?	To take part in the study, participants must: • Be 55 to 80 years old • Have cognitive complaints or objective memory impairment and is being evaluated for Alzheimer's disease and other causes of cognitive decline, for which the cause is yet unknown, or would be in need of referral for further cognitive evaluation • Have a score between 0.5 to 12 in the Quick Dementia Rating System (QDRS) questionnaire, with one domain representing memory and recall • Have no contraindication for performing: clinical interview, cognitive testing, blood and CSF extraction and/or amyloid PET scan • Have a study partner who has sufficient contact with the participant (minimum twice a week), is willing to participate in a clinical interview for this study, is fluent in the language

	used during the assessment, and has sufficient cognitive health themselves to provide accurate information • Sign informed consent form. The following criteria are allowed and should not be used to exclude participants: • Presence of comorbidity and concurrent non-acute medical illness • Presence of concurrent psychiatric illness or history of psychiatric disorder • Concurrent use of mood stabilizing drugs or other medications to treat psychiatric symptoms • Presence of alcohol or substance abuse • Concomitant medications and comorbidities (e.g. controlled diabetes, thyroid disorders, vitamin B12 deficiency) • History of stroke or seizures within 1 year of screening visit or/and history of cancer within the past 5 years (if it is not clear if these are cause of their cognitive concerns) • History of head trauma.
Who cannot participate in the study?	Exclusion criteria: • Clinical diagnosis of moderate and severe dementia and/or Mini-Mental State Exam (MMSE) score <20 • Advanced diagnostic evaluation including amyloid PET and/or tau PET and/or CSF as part of the routine medical care • Presence of active delirium or encephalopathy (disturbance of the brain's functioning) • Any condition that, in the opinion of the investigator, could interfere with the study and its procedures

	• Have participated in a recent clinical study within the last six months with the use of other investigational treatments (or 5 half-lives whichever is longer) • Use of anti-amyloid medication in a clinical trial or at any time in the life.

5. Where and when will the study be conducted?	
European countries involved in the trial	• Austria • Denmark • Germany • Spain • UK
Estimated start date of recruitment	May 2023

6. Information	
Study contact information	David Caley, Global Study Lead David.caley@contractors.roche.com

✓ This document has been reviewed by the company running the study.