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Clinical performance study of the in vitro diagnostic device Elecsys® Amyloid Plasma Panel

Submission date
07/08/2024

Recruitment status
No longer recruiting

Registration date
07/10/2024

Overall study status
Completed

Last Edited
20/10/2025

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This global study aims to see how well a new blood test, the Elecsys® Amyloid Plasma Panel (EAPP), can identify how likely people with memory problems are to develop Alzheimer's disease (AD). To do so, the test identifies toxic proteins, such as amyloid, which build up in the brains of people with AD and are key characteristics in identifying people who have or are at risk of AD. AD is an illness in the brain that causes memory problems, as well as difficulties with thinking and reasoning. It can also affect behaviour and the ability to carry out normal activities. AD is a potentially serious medical condition and not part of normal ageing. The EAPP may allow faster access to medical, personal, and emotional support, and opportunities to take part in research for people with memory problems.

Who can participate?
Males and females between the ages of 55 and 80 years who are experiencing issues with their memory, thinking and reasoning, and have not previously had a diagnosis of dementia

What does the study involve?
Participants will need to visit their study centre up to four times over a period of 3 months for procedures such as assessments of their memory and thinking, a clinical assessment, blood collection, brain imaging by PET and MRI scans, and a lumbar puncture.

What are the possible benefits and risks of participating?
The results from this study will be used to receive regulatory approval of the EAPP for use with patients with memory problems in clinics around the world. Since there is no intervention (drug) given in this study, the risks are low for the participants. Study participants may have accelerated access to Alzheimer's diagnostics than they would get in routine care.

Where is the study run from?
Roche Diagnostics (Switzerland)

When is the study starting and how long is it expected to run for?
January 2022 to December 2024

Who is funding the study?
Roche Diagnostics (Switzerland)

Who is the main contact?
David Caley, david.caley@contractors.roche.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Mr David Caley

Contact details
Forrenstrasse 2
Rotkreuz
Switzerland
6343
+44 (0)7731325977
david.caley@contractors.roche.com

Additional identifiers

Integrated Research Application System (IRAS)
326591

Central Portfolio Management System (CPMS)
57697

Protocol serial number
RD006263

Study information

Scientific Title
A multicenter, prospective, non-interventional study to determine the cutoff and clinical performance of the Elecsys® Amyloid Plasma Panel and its component assays

Acronym
EAPP

Study objectives
Firstly to derive the stepwise decision function for the Elecsys® Amyloid Plasma Panel (EAPP), and to calculate a cut-off for the Elecsys® Phospho-Tau (181P) plasma (pTau181p) immunoassay, which maximizes the clinical performance of each in the intended use population.

Then, to demonstrate the Clinical Performance of both EAPP and pTau181p in terms of their ability to rule out subjects in the intended use population, who are most likely to be amyloid negative, by showing a high negative predictive value (NPV) and acceptable positive predictive value (PPV).

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 18/07/2023, London - Stanmore Research Ethics Committee (2nd Floor, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048068; stanmore.rec@hra.nhs.uk), ref: 23/LO/0483

2. Approved 12/12/2023, Ethikkommission Bei Der Lmu München (Pettenkoferstr. 8a, Munich, 80336, Germany; +49 (0)89 440055191; Ethikkommission@med.uni-muenchen.de), ref: 23-0869 fed

3. Approved 31/08/2023, Ethikkommission der Medizinischen Universität Wien (Borschkegasse 8b/6, Vienna, 1090, Austria; +43 (0)1 404 00-21470, 22440; ethik-kom@meduniwien.ac.at), ref: 1267/2023

4. Approved 24/04/2023, Medical Research Ethics Committees (Ørestads Boulevard 5, Bygning 37K, st., Copenhagen, 2300, Denmark; +45 (0)72 21 66 77; kontakt@dvmk.dk), ref: 2303725

5. Approved 05/04/2023, Comité de Ética de la Investigación con medicamentos del Parc de Salut MAR (Dr. Aiguader, 88, Barcelona, 08003, Spain; +34 (0)93 316 06 77; ceic-psmar@imim.es), ref: 2023/10799

6. Approved 04/04/2023, WCG IRB (1019 39th Ave SE/ Suite 120, Puyallup, 98374, United States of America; +1 (0)855 818 2289; clientcare@wcgclinical.com), ref: 2023/10799

7. Approved 22/02/2024, Bellberry IRB (123 Glen Osmond Road, Eastwood, 5063, Australia; +61 (0)8 8361 3222; bellberry@bellberry.com.au), ref: 2023-10-1246

Primary study design
Observational

Study design
Observational multi-centre cross-sectional study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Alzheimer's disease, amyloid pathology

Interventions
The duration of participation of each patient is approximately four visits over 3 months. Two study arms; cutoff establishment and pivotal clinical trial. Please note that both arms have the same methodology - only the objectives and therefore the statistical analyses differ between the two arms. There is no randomisation, sites are assigned to either one of the two arms, so

patients are enrolled into the arm that their site is assigned. All potential participants will be screened - involving informed consent, an assessment against the inclusion and exclusion criteria (including administration of QDRS and MMSE) and collection of demographic information. Subjects who are screened in will have the following procedures over approximately three further visits: clinical interview, administration of Clinical Dementia Rating scale, vitals collection, blood collection (for measurement with EAPP and creatinine, and APOE genotyping, if applicable), CSF collection (for measurement with Elecesys AB42 and pTau181 biomarkers) and /or amyloid PET and MRI (T1w, T2, FLAIR).

Intervention Type
Other

Primary outcome(s)
Clinical performance of EAPP and pTau181p in reference to amyloid pathology status as defined by amyloid PET imaging VR. All measures are conducted at a single timepoint.

Key secondary outcome(s)
1. Clinical performance of EAPP and pTau181p in reference to amyloid pathology status as defined by CSF biomarker analysis. All measures are conducted at a single timepoint.
2. Clinical performance of ApoE4p sub-result in reference to amyloid pathology status as defined by APOE4 genetic carrier status. All measures are conducted at a single timepoint.

Completion date
17/12/2024

Eligibility

Key inclusion criteria
1. 55 to 80 years old (inclusive) at the time of ICF signature
2. Has cognitive complaints or objective memory impairment and is being evaluated for Alzheimer's Disease (AD) and other causes of cognitive decline, for which the cause is yet unknown, or would be in need of referral for further cognitive evaluation
3. Quick Dementia Rating System (QDRS) score from 0.5 to 12 (inclusive), with one box memory and recall
4. PI has uncertainty about the underlying etiology i.e. not certain that symptoms are caused by AD
5. No contraindication for performing: clinical interview, cognitive testing, blood and CSF extraction and/or amyloid PET scan
6. Has a person available to be an informant for the Clinical Dementia Rating. An informant can be any person with sufficient contact with the patient (minimum twice a week), who 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 to provide accurate information.
7. Signed informed consent form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Other

Lower age limit
55 Years

Upper age limit
80 Years

Sex
All

Key exclusion criteria
1. A clinical diagnosis of moderate and severe dementia and/or Mini-Mental State Exam (MMSE) score <20
2. Has already undergone advanced diagnostic evaluation including amyloid PET and/or tau PET and/or CSF as part of their routine medical care
3. Presence of active delirium or encephalopathy
4. Shows any condition that, in the opinion of the investigator, could interfere in the proper execution of the study procedures and/or in their future permanence in the study
5. Has received or is receiving any investigational treatment within 5 half-lives or 6 months (whichever is longer) prior to enrollment and during the course of this study before their participation is complete
6. Has received any anti-amyloid medication in a clinical trial setting or other at any time in their life

Date of first enrolment
20/05/2023

Date of final enrolment
30/09/2023

Locations

Countries of recruitment
United Kingdom

England

Scotland

Australia

Austria

Denmark

Germany

Spain

United States of America

Study participating centre
Brain Health Scotland Life Sciences Ltd
Gyleview House
3 Redheughs Rigg
Edinburgh
United Kingdom
EH12 9DQ

Study participating centre
King's College Hospital
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
Australian Dementia Network
Melbourne
Australia
3010

Study participating centre
Adams Clinical
Watertown
United States of America
02472

Study participating centre
Alzheimer's Research and Treatment Center
Wellington
United States of America
33414

Study participating centre
Barrow Neurological Institute
Pheonix
United States of America
85013

Study participating centre
Center for Advanced Research & Education
Gainesvill
United States of America
30501

Study participating centre
Charter Research
Lady Lake
United States of America
32159

Study participating centre
Charter Research
Winter Park
United States of America
32792

Study participating centre
Eastside Research
Redmond
United Kingdom
98052

Study participating centre
K2 Medical Research
Tampa
United States of America
33607

Study participating centre
K2 Medical Research
Maitland
United States of America
32751

Study participating centre

K2 Medical Research
The Villages
United States of America
32159

Study participating centre
Genesis Neuroscience Clinic
Knoxville
United Kingdom
37909

Study participating centre
Indiana University Health
Indianapolis
United States of America
46202

Study participating centre
Massachusetts General Hospital
Boston
United Kingdom
02114

Study participating centre
Optimus U
Miami
United States of America
33135

Study participating centre
Berman Clinical
New York City
United States of America
10029

Study participating centre

Barcelona-beta Research Center
Barcelona
Spain
08005

Study participating centre
ACE Alzheimer Center
Barcelona
Spain
08028

Study participating centre
Vall D'Hebron University Hospital
Barcelona
Spain
08035

Study participating centre
Universitätsklinikum RWTH Aachen
Aachen
Germany
52074

Study participating centre
Charite Ambulantes Gesundheitszentrum
Berlin
Germany
10117

Study participating centre
Universitätsklinikum Köln
Köln
Germany
50937

Study participating centre

Studienzentrum Dr. Bischof GmbH
Böblingen
Germany
71034

Study participating centre
Institut für Studien zur Psychischen Gesundheit
Mannheim
Germany
68165

Study participating centre
Danish Dementia Research Center
Copenhagen
Denmark
2100

Study participating centre
MedUni Wien
Vienna
Austria
1090

Study participating centre
Universitätsklinikum Salzburg
Salzburg
Austria
5020

Sponsor information

Organisation
Roche Diagnostics International Ltd

Funder(s)

Funder type

Industry

Funder Name
Roche Diagnostics International Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date