Moses II - Measuring Elecsys β-Amyloid (1-42) II and Phospho-Tau (181P) in CSF Samples supporting Phase 2 Clinical Trial of 247AD201 (BIIB080)

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The primary objective of the diagnostic study is to analyze the CSF measurements of β-Amyloid (1-42) (Aβ 42) and Phospho-Tau (181P) (pTau) using Elecsys β-Amyloid (1-42) CSF II and Elecsys Phospho-Tau (181P) CSF in the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Mental impairment disorders
Study type	Interventional

Summary

ID

NL-OMON57028

Source
ToetsingOnline

Brief title
Moses II

Condition

- Mental impairment disorders

Synonym
dementia, mild cognitive impairment

Research involving
Human

Sponsors and support

Primary sponsor: Roche Diagnostics International Ltd

Source(s) of monetary or material Support: funded by sponsor

Intervention

Keyword: N/A

Outcome measures

Primary outcome

The ratio of β-Amyloid (1-42) (Aβ 42) and Phospho-Tau (181P) (pTau) in the

screening samples of the phase 2 clinical trial of 247AD201 (BIIB080)

Secondary outcome

Not applicable

Study description

Background summary

This diagnostic study is conducted in association with the pharma phase 2 clinical trial titled *A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Assess the Efficacy, Safety, and Tolerability of BIIB080 in Subjects with Mild Cognitive Impairment Due to Alzheimer*s Disease or Mild Alzheimer*s Disease Dementia (Protocol Number: 247AD201)*. In this pharmaceutical trial, the drug BIIB080 is being investigated in adult subjects with mild cognitive impairment (MCI) due to AD or mild AD mild AD dementia.

Roche Diagnostics has developed diagnostic biomarker assays to measure the β-Amyloid (1-42) and Phospho-Tau (181P) levels in CSF (cerebrospinal fluid) samples. The ratio between β-Amyloid (1-42) and Phospho-Tau (181P) is evidence for amyloid pathology, one of the hallmarks of Alzheimers Disease (AD). Based on the ratio between β-Amyloid (1-42) and Phospho-Tau (181P) in CSF screening samples patients will be included in the pharmaceutical trial.
Moses II is the code name for the diagnostics study in support of the pharma phase 2 clinical trial.

Study objective

The primary objective of the diagnostic study is to analyze the CSF measurements of β-Amyloid (1-42) (Aβ 42) and Phospho-Tau (181P) (pTau) using Elecsys β-Amyloid (1-42) CSF II and Elecsys Phospho-Tau (181P) CSF in the

screening samples of the phase 2 clinical trial of 247AD201 (BIIB080) to enroll patients based on the pTau/Aβ 42 ratio as evidence of amyloid pathology.

Study design

Clinical Utility Study (Interventional Study according to IVDR)

Intervention

Not applicable, CSF samples will be obtained from patients under the pharma protocol.

Study burden and risks

There is no direct personal benefit to participating in the performance (Moses II) study. Patients are not paid for participation in the performance study. There is minimal/no risk associated with testing the CSF sample; the patient does not have to undergo any new procedures to have his/her CSF sample tested. However, the information obtained by testing the CSF sample may partially determine the patient's eligibility to participate in the pharmaceutical study.

Contacts

Public
Roche Diagnostics International Ltd

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Scientific
Roche Diagnostics International Ltd

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In the present study, CSF samples collected for screening for the associated pharma trial will be measured. No further patient inclusion criteria apply. Specifically, the CSF samples will be collected from subjects with either MCI due to AD or mild AD dementia who meet the screening criteria as described in the pharma phase 2 clinical trial protocol and are able to undergo CSF sampling at screening. Please see the pharma clinical trial protocol for patient inclusion and exclusion criteria for the clinical trial.

Approximately 600 subjects will be screened via CSF in order to test for eligibility and randomize the planned quantity of subjects in the pharma trial.

CSF specimen eligibility criteria for the performance study:

- frozen at sample receipt
- not visibly hemolyzed
- approx. 500µl sample volume

Exclusion criteria

In the present study, CSF samples collected for screening for the associated pharma trial will be measured. No further patient exclusion criteria apply.

CSF specimen eligibility criteria for the performance study:

- frozen at sample receipt
- not visibly hemolyzed
- approx. 500µl sample volume

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-02-2023
Enrollment:	3
Type:	Actual

Medical products/devices used

Generic name:	Elecsys β□Amyloid (1□42) CSF II and Elecsys Phospho-Tau (181P) CSF
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	05-03-2024
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL83517.000.23