A Phase 2 Multiple Dose, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of ABBV-8E12 in Subjects with Early Alzheimer's Disease

Published: 04-10-2017
Last updated: 25-03-2025

1. To assess the efficacy of ABBV-8E12 in slowing disease progression (cognitive and functional impairment) in subjects with Early Alzheimer's Disease (AD) as measured by the Clinical Dementia Rating - Sum of Boxes (CDR-SB).2. To assess the...

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48538

Source
ToetsingOnline

Brief title
M15-566

Condition

- Other condition

Synonym
Alzheimer's, Alzheimer's disease

Health condition

Neurologisch

Research involving
Human

Sponsors and support

Primary sponsor: AbbVie B.V.
Source(s) of monetary or material Support: AbbVie

Intervention

Keyword: Alzheimer's disease, Monoclonal antibody ABBV-8E12, Tau-protein

Outcome measures

Primary outcome

Primary endpoint: CDR-SB at week 96.

Secondary outcome

Secondary endpoints are determined by various assessments: PK, MMSE,

ADAS-Cog-14, RBANS, ADCS-MCI-ADL-24, FAQ, UPSA-B, ADCS-CGIC-MCI. This will be

determined at 96 weeks.

Study description

Background summary

Alzheimer's disease (AD) is the most prevalent neurodegenerative disease among the elderly population and the most common cause of dementia. At present, approved pharmacological therapy for AD consists of symptomatic treatment. Thus, there is a medical need for treatment modifying the course of the disease on a biological level.
ABBV-8E12 is a humanized antibody being studied to target the tau protein, which is thought to stabilize intracellular structures required for maintenance and transport in neurons. Abnormal accumulation of altered tau protein is a hallmark in a variety of neurodegenerative conditions, where the development of tau pathology strongly correlates with clinical disease progression.

Study objective

1. To assess the efficacy of ABBV-8E12 in slowing disease progression

(cognitive and functional impairment) in subjects with Early Alzheimer's Disease (AD) as measured by the Clinical Dementia Rating - Sum of Boxes (CDR-SB).
2. To assess the long term safety of ABBV-8E12 for up to 96 weeks in subjects with Early AD.

Study design

A phase-2, multiple dose, multicenter, multinational, randomized, double-blind, placebo-controlled study designed to evaluate the efficacy and safety of ABBV-8E12 in subjects with Early Alzheimer's disease. The study will consist of a screening period, a 96-week double-blind treatment period and a follow-up period of approximately 20 weeks following the last study drug administration.

Intervention

Subjects will be randomized to one of the 3 dose arms or placebo in a 1:1:1:1 ratio.

Study burden and risks

Subjects participating in this trial will experience a higher burden compared to standard of care. The subject will visit the hospital more frequent and spend more time during visits. Subject will receive IV infusion of ABBV-8E12 or placebo and undergo various procedures; these include blood sampling and questionnaires.

So far, no notable safety findings were discovered. The benefit risk profile will be further defined in this trial.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Subject who meets the National Institute on Aging and the Alzheimer's Association (NIA-AA) clinical criteria for mild cognitive impairment or probable AD, and have:
- Clinical Dementia Rating (CDR)-Global Score of 0.5
- Mini-Mental State Examination (MMSE) score of 22 to 30, inclusive
- Repeatable Battery for the Assessment of Neuropsychological Status-Delayed Memory Index (RBANS - DMI) score of 85 or lower
* Subject has a positive amyloid Positron Emission Tomography (PET) scan.
* Subject has a Modified Hachinski Ischemic Scale (MHIS) score of 4.
* The subject has an identified, reliable, study partner (e.g., family member).
* If using medications to treat symptoms related to AD, doses must be stable for at least 12 weeks prior to randomization.

Exclusion criteria

* Subject has any contraindications or inability to tolerate to brain magnetic resonance imaging (MRI), PET scans or lumbar puncture (optional).
* Subject has evidence of any other clinically significant neurological disorder other than Early AD.
* In the opinion of the investigator, the subject has any clinically significant or uncontrolled medical or psychiatric illness, or has had an infection requiring medical intervention in the past 30 days.
* Subject has had a myocardial infarction, unstable angina, stroke, transient ischemic attack or required intervention for any of these conditions within 6 months of screening Visit 1.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	11-12-2018
Enrollment:	7
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	ABBV-8E12
Generic name:	ABBV-8E12

Ethics review

Approved WMO Date:	04-10-2017
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	24-04-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek

	(Assen)
Approved WMO Date:	09-05-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	16-07-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	16-01-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-05-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	29-07-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	16-06-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	05-11-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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
Other	02880956
EudraCT	EUCTR2016-001634-10-NL
CCMO	NL62386.056.17

Study results

Date completed: 16-02-2021

Results posted: 17-08-2022

Actual enrolment: 7

First publication
05-07-2022

URL result
URL
Type
int
Naam
M2.2 Samenvatting voor de leek
URL

Internal documents
File