

What to Expect During the Early Alzheimer's Study

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Study Purpose: Inform Prospective Clinical Trial Participants What to Expect
Study Name: Evaluate the Efficacy and Safety of ABBV-8E12 in Subjects w/ Early Alzheimer's
Disease Study Conductors: National Institutes of Health/US Federal Government

Study Sponsor/Client: AbbVie Style Guide Used: Chicago Manual of Style
Workflow Used: Basecamp Study Results: clinicaltrials.gov

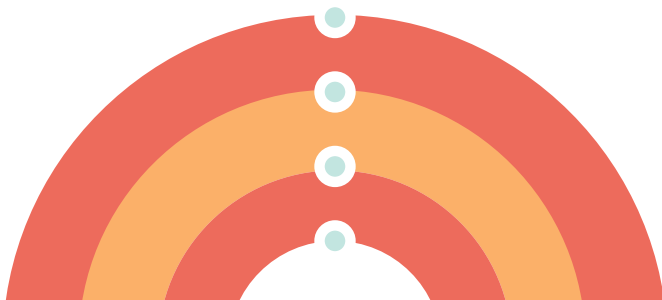
Results:90% of My Corrections/Edits Were Accepted by AbbVie Team, Who Often Reject Them

The **Aware Study** Visit Guide

What to Expect During the **Early Alzheimer's Study**

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Study Overview

The study will last about 2 years. During this time, you will visit our office about 31 times.

There are 3 phases to the Aware Study:

- Screening
- Treatment
- Follow-up

At this point, you've already finished the first part of the study, Screening.

In the Treatment and Follow-up phases, the study team will perform different tests and procedures to find out if ABBV-8E12 is safe and effective. The study team, along with the study doctor, will monitor your health closely.

Treatment

The Treatment phase of the study lasts 96 weeks, during which time you'll need to come to our office for study visits every four weeks. If you are part of the first 48 patients to enroll, you'll need to come for 4 additional appointments.

Most study visits will take about 4 hours, though a few may take 6–8 hours.

During your appointment you'll receive the investigational medication through an intravenous (IV) infusion, which will take between 1-2.5 hours depending on your weight; there is also a post-infusion observation period. At some of your appointments, you and your study partner will be asked questions about your symptoms, health and medications. This part of the appointment will take several hours.

Some study visits may include the following tests and procedures:

- Physical exams
- Neurological exams
- Vital signs
- Blood and urine tests
- Electrocardiogram (ECG)
- MRI scan of the brain
- Lumbar puncture

Follow-up

After your final dose of the investigational medication, you'll have about 3 more visits over about 4-5 months.

In order to make sure you're safe, as well as to see if ABBV-8E12 may slow the progression of Alzheimer's disease, we will do some of the same procedures and tests as in the Treatment phase of the study.

Your Study Partner

Your study partner will need to attend some study visits. Since your study partner is someone who knows you well, he or she may notice slight changes before you do and will need to tell us about them during the visit.

Reminders About Medications

There are certain types of medications that you will not be able to take during the study.

Do not start any new medications without telling your study doctor.

Tell your study doctor right away about any changes to your medications.

This includes:

- New prescription or over-the-counter medications as well as supplements
- Changes to medications or doses, or stopping a medication



Study Tests and Procedures

The following tests and procedures will be administered during the study.



Intravenous (IV) Infusion

The investigational medication will be administered through an intravenous (IV) infusion. This will take 1 to 2.5 hours, depending on your weight.

There are 24 IV infusions during the study.



Questionnaires/Evaluations

Some of the questions you'll be answering include:

Memory and function: You will answer questions and take tests relating to your memory, thinking, learning and how you are able to function. Your study partner will also provide information on your memory and how you are able to function. The study team will record audio during some of these tests. Your name will not be used.

Daily life and mood: You and your study partner will answer questions about your mood, emotional state and everyday life.

Health: You'll be asked about your general health and common habits, like using alcohol or tobacco.

Medications: Your study team will keep a list of all medications you are taking, including over-the-counter and supplements.



Physical Exams, Neurological Exams and Vital Signs

Physical exam: A general check-up of your body.

Neurological exam: A simple and painless check-up on your nervous system (brain, spinal cord and nerves).

Vital signs: The checking of your temperature, pulse, breathing and blood pressure.



Blood and Urine Tests

We will take blood and urine samples to learn about your overall health and any signs of disease.

Some blood tests will require that you fast beforehand, so you will not be able to eat or drink anything except water for 8 hours before the study visit. Your Study Visit Calendar indicates when you have to do this and your study team will also remind you beforehand.



Electrocardiogram (ECG)

This painless test records the electrical activity of your heartbeat and gives us information about your heart.



MRI Scans of the Brain

MRI, or magnetic resonance imaging, is a painless procedure that uses strong magnets to capture detailed images of the brain.

There are 8 MRIs during the study, including the one you had during screening.



Lumbar Puncture

A lumbar puncture is a test where a needle is used to collect fluid that surrounds the spinal cord. A study doctor will numb the area of your lower back and insert

a needle to draw out the spinal cord fluid. This fluid will give researchers information about how the investigational medication is working.

The lumbar puncture takes about 45 minutes and you will need to stay in bed for about an hour afterwards.

There are 2-3 lumbar punctures during the study, including the one you had during screening.

Most Common Tests and Procedures

This chart shows the most common tests and procedures in the study.

What to Expect During Study Visits			
Every visit	Most visits	Many visits	Some visits
Questions about your health and medications, including the investigational medication	IV infusion (every visit during the Treatment phase of the study)	ECG	Questions about your memory, daily life and mood
Vital signs (except for the last visit)	Neurological exam	Urine test	MRI
	Blood test		

Study Visit Calendar

Please bring a list of your medications, including over-the-counter and supplements, to every study visit.

Every visit will include:

- Vital signs (pulse, temperature and blood pressure)
- Review of general health
- Review of medications you're taking (prescription, over-the-counter and supplements)

Study visit activities that are only done at some visits are noted under each visit below.

Some activities may be scheduled on a different day than the IV infusion.



If you are part of Cohort 1, you will need to attend the visits listed next to a target for additional safety testing.

If you can't make it to an appointment, please call the study staff immediately. Phone numbers are listed at the end of this guide.

Year 1

Treatment Period

DOSE 1 (DAY 1)

Date: ____ / ____ / ____ Time: ____ AM / PM

Length of this study visit: ____ hours

Your study partner needs to attend this visit.

Please fast (no food or drink for 8 hours before visit).

This visit will include:

- IV infusion
- Memory testing and questions
- Study partner questions
- Neurological exam
- ECG
- Blood draw



**Cohort 1
Only**

DOSE 1 (DAY 5)

Date: ____ / ____ / ____ Time: ____ AM / PM

Length of this study visit: ____ hours

- No IV infusion this visit
- Neurological exam
- ECG
- Blood draw



**Cohort 1
Only**

DOSE 1 (DAY 15)

Date: ____ / ____ / ____ **Time:** _____ AM / PM

Length of this study visit: _____ hours

- No IV infusion this visit
- Neurological Exam
- ECG
- Blood Draw

DOSE 2 (DAY 29)

Date: ____ / ____ / ____ **Time:** _____ AM / PM

Length of this study visit: _____ hours

Please fast (no food or drink for 8 hours before visit).

This visit will include:

- IV infusion
- MRI
- Neurological exam
- ECG
- Blood draw

DOSE 3 (DAY 57)

Date: ____ / ____ / ____ **Time:** _____ AM / PM

Length of this study visit: _____ hours

Please fast (no food or drink for 8 hours before visit).

This visit will include:

- IV infusion
- Neurological exam
- ECG
- Blood draw

DOSE 4 (DAY 85)

Date: ____ / ____ / ____ Time: _____ AM / PM

Length of this study visit: _____ hours

Please fast (no food or drink for 8 hours before visit).

This visit will include:

- IV infusion
 - MRI
 - Neurological exam
 - ECG
 - Blood draw
 - Lumbar puncture
- Optional Required



Cohort 1
Only

DOSE 4 (DAY 89)

Date: ____ / ____ / ____ Time: _____ AM / PM

Length of this study visit: _____ hours

- No IV infusion this visit
- Neurological exam
- Blood draw



Cohort 1
Only

DOSE 4 (DAY 99)

Date: ____ / ____ / ____ Time: _____ AM / PM

Length of this study visit: _____ hours

- No IV infusion this visit
- Neurological exam
- Blood draw

DOSE 5 (DAY 113)

Date: ____ / ____ / ____ Time: _____ AM / PM

Length of this study visit: _____ hours

Please fast (no food or drink for 8 hours before visit).

This visit will include:

- IV infusion
- Blood draw
- Neurological exam

DOSE 6 (DAY 141)

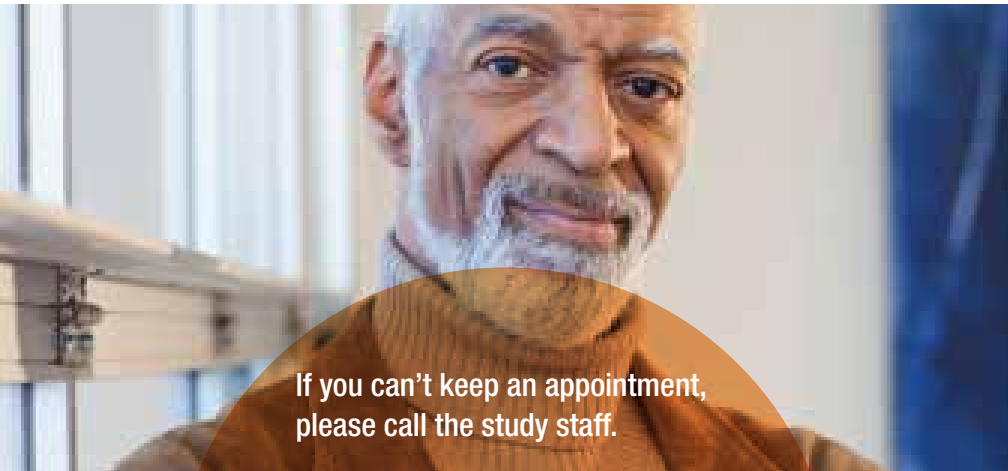
Date: ____ / ____ / ____ Time: _____ AM / PM

Length of this study visit: _____ hours

Please fast (no food or drink for 8 hours before visit).

This visit will include:

- IV infusion
- Blood draw
- Neurological exam



If you can't keep an appointment,
please call the study staff.

DOSE 7 (DAY 169)

Date: ____ / ____ / ____ Time: _____ AM / PM

Length of this study visit: _____ hours

Your study partner needs to attend this visit.

Please fast (no food or drink for 8 hours before visit).

This visit will include:

- IV infusion
- Memory testing and questions
- Study partner questions
- Neurological exam
- ECG
- Blood draw

DOSE 8 (DAY 197)

Date: ____ / ____ / ____ Time: _____ AM / PM

Length of this study visit: _____ hours

This visit will include:

- IV infusion
- MRI

DOSE 9 (DAY 225)

Date: ____ / ____ / ____ Time: _____ AM / PM

Length of this study visit: _____ hours

This visit will include:

- IV infusion

DOSE 10 (DAY 253)

Date: ____ / ____ / ____ Time: _____ AM / PM

Length of this study visit: _____ hours

Please fast (no food or drink for 8 hours before visit).

This visit will include:

- IV infusion
- Neurological exam
- ECG
- Blood draw

DOSE 11 (DAY 281)

Date: ____ / ____ / ____ Time: _____ AM / PM

Length of this study visit: _____ hours

This visit will include:

- IV infusion
- Neurological exam

DOSE 12 (DAY 309)

Date: ____ / ____ / ____ Time: _____ AM / PM

Length of this study visit: _____ hours

This visit will include:

- IV infusion
- MRI
- Neurological exam

DOSE 13 (DAY 337)

Date: ____ / ____ / ____ Time: _____ AM / PM

Length of this study visit: _____ hours

Your study partner needs to attend this visit.

Please fast (no food or drink for 8 hours before visit).

This visit will include:

- IV infusion
- Memory testing and questions
- Study partner questions
- Neurological exam
- ECG
- Blood draw

Year 2

Treatment Period (continued)

DOSE 14 (DAY 365)

Date: ____ / ____ / ____ Time: _____ AM / PM

Length of this study visit: _____ hours

This visit will include:

- IV infusion

DOSE 15 (DAY 393)

Date: ____ / ____ / ____ Time: _____ AM / PM

Length of this study visit: _____ hours

This visit will include:

- IV infusion

DOSE 16 (DAY 421)

Date: ____ / ____ / ____ Time: _____ AM / PM

Length of this study visit: _____ hours

Please fast (no food or drink for 8 hours before visit).

This visit will include:

- IV infusion
- Blood Draw
- Neurological exam

DOSE 17 (DAY 449)

Date: ____ / ____ / ____ Time: _____ AM / PM

Length of this study visit: _____ hours

This visit will include:

- IV infusion

DOSE 18 (DAY 477)

Date: ____ / ____ / ____ Time: _____ AM / PM

Length of this study visit: _____ hours

This visit will include:

- IV infusion
- MRI

DOSE 19 (DAY 505)

Date: ____ / ____ / ____ Time: _____ AM / PM

Length of this study visit: _____ hours

Your study partner needs to attend this visit.

Please fast (no food or drink for 8 hours before visit).

This visit will include:

- IV infusion
- Memory testing and questions
- Study partner questions
- Neurological exam
- ECG
- Blood Draw

DOSE 20 (DAY 533)

Date: ____ / ____ / ____ Time: _____ AM / PM

Length of this study visit: _____ hours

This visit will include:

- IV infusion

DOSE 21 (DAY 561)

Date: ____ / ____ / ____ Time: _____ AM / PM

Length of this study visit: _____ hours

This visit will include:

- IV infusion

DOSE 22 (DAY 589)

Date: ____ / ____ / ____ Time: _____ AM / PM

Length of this study visit: _____ hours

Please fast (no food or drink for 8 hours before visit).

This visit will include:

- IV infusion
- Blood Draw
- Neurological exam

DOSE 23 (DAY 617)

Date: ____ / ____ / ____ Time: _____ AM / PM

Length of this study visit: _____ hours

This visit will include:

- IV infusion

DOSE **24** (DAY 645)

Date: ____ / ____ / ____ **Time:** _____ AM / PM

Length of this study visit: _____ hours

This visit will include:

- IV infusion

COMPLETION VISIT

Date: ____ / ____ / ____ **Time:** _____ AM / PM

Length of this study visit: _____ hours

Your study partner needs to attend this visit.

Please fast (no food or drink for 8 hours before visit).

This visit will include:

- Memory testing and questions
- Study partner questions
- MRI
- Lumbar puncture
- Neurological exam
- ECG
- Blood Draw

FOLLOW-UP VISIT (DAY 729)

Date: ____ / ____ / ____ **Time:** _____ AM / PM

Length of this study visit: _____ hours

Please fast (no food or drink for 8 hours before visit).

This visit will include:

- MRI
- ECG
- Neurological exam
- Blood Draw

FOLLOW-UP VISIT (DAY 785)

Date: ____ / ____ / ____ **Time:** _____ AM / PM

Length of this study visit: _____ hours

- Blood Draw



If you can't keep an appointment,
please call the study staff.

Notes

(Please use this section to record any medications, symptoms or comments that need to be discussed with the study team)

Notes

Who to Contact with Questions

If you have questions, please call your study doctor or other members of the study team.

Your study doctor is:

Name: _____

Phone number: _____

Your study coordinator is:

Name: _____

Phone number: _____

