Can I change my mind?

Yes. You can quit the study at any time, for any reason. Even if you begin the study, you can change your mind at any point.

For more information about this clinical research study, you may visit www.clinicaltrials.gov and search "63733657ALZ2002" or visit www.autonomystudy.com to see if you may be eligible.

You may also contact the study center for more information:

Janssen Research & Development, LLC
63733657ALZ2002-ENG08 INT-2 Version 1.0, 28Mar2022

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Information Brochure

A Clinical Research Study to Evaluate an Investigational Medicine in People Experiencing Problems with Memory or Trouble Thinking Clearly is Now Enrolling.

Autonomy
ANTI-TAU ANTIBODY STUDY FOR ALZHEIMER'S DISEASE

Janssen

What is a clinical research study?

A clinical trial, also called a clinical research study, is a carefully designed scientific evaluation of an investigational medicine or treatment. Clinical trials are conducted by doctors and researchers.

Why is clinical research important?

Clinical research helps doctors and scientists determine if an investigational medicine or therapies are safe and/or effective for use in humans to potentially treat a condition, disease, or disorder. Research has shown that certain diseases and medications may impact people differently based on their age, gender, and genetic background, including race and ethnicity. Therefore, clinical studies often require large numbers of diverse volunteers to participate in a single study, sometimes thousands are needed to obtain reliable information.

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What is Informed Consent?

"Informed Consent" is a process of information exchange before an adult agrees to participate in research. Potential research participants will be asked to read and sign an Informed Consent document. They will also be given instructions, verbally and in writing, question/answer sessions, and other reading materials to assure the potential study participant's understanding and willingness to voluntarily enroll in the research.

So before you agree to volunteer for the study, the study doctor or study team is required to explain all the details of the study, which will include the potential risks and potential benefits, and address your questions.

After all of your questions have been answered, and if you wish to participate, then you will sign a document called the Informed Consent Form to ensure:

- You agree to volunteer
- You understand the study, including the study procedures, risks, and potential side effects of the investigational medicine
- You understand that you can leave the study at any time, for any reason.

If you don't understand what is expected of you or the document, you should continue to ask questions and talk with the study doctor, your family, or others that you trust, until you feel you understand.

For this study, you will need a friend or relative (study partner) who can accompany you to your study visits. They will also need to sign an Informed Consent Form.

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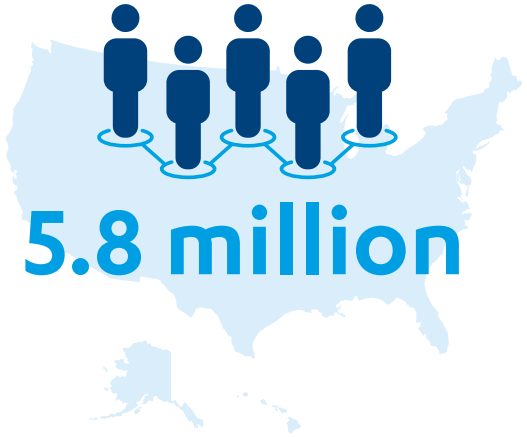

Purpose of the Autonomy Study

The purpose of this study is to see how safe an investigational medicine is, and whether it is effective for people with early Alzheimer's disease (AD).

We are looking for people who have memory problems and trouble thinking clearly.

According to the Centers for Disease Control and Prevention (CDC), about 5.8 million people in the United States have AD and related dementia. Data suggest that Hispanics, Latinos, and Blacks (African-Americans) may be at increased risk of developing AD due to underlying medical conditions.[1]

1. Diversity and Disparity in Dementia: The Impact of Ethnoracial Differences in Alzheimer's Disease. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3396146/. Accessed 21 January 2021.

Tau is a protein found in the brain. In people with AD, an abnormal form of tau builds up in the brain and may cause memory loss. If you meet all study eligibility criteria, the presence of abnormal tau in your brain will be evaluated.

The study will evaluate if the investigational medicine binds to abnormal tau to stop abnormal tau from spreading in the brain, and slow memory loss.

The investigational medicine will be compared with a placebo during this study.

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What is a placebo?

In the Autonomy Study, some participants will receive a placebo instead of the investigational medicine. A placebo looks just like the investigational medicine and is given in the same way, but it does not contain any active ingredients. Using a placebo in the study may show the potential differences between the investigational medicine and the placebo. Regardless of whether the investigational medicine works or not, your participation and the results of this study may help us to learn more about early AD.

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Am I eligible?

You may be able to participate in this study if you:

- are 55–80 years of age
- are experiencing a gradual decline in your cognitive abilities (e.g. memory, problem-solving skills, and ability to pay attention and think clearly) over at least the past 6 months or have been diagnosed with early AD (also known as mild cognitive impairment due to AD, prodromal AD, or mild AD dementia)
- have a reliable close friend, relative, or spouse who can be your study partner. This should be someone who:
  - spends at least 10 hours every week with you
  - knows your daily functioning well
  - is able to accompany you to study center visits
  - must be available for a telephone call with the study team for visits not requiring study partner attendance, if someone other than the study partner accompanies you to a visit.

55–80

The study doctor or study team will check additional eligibility criteria during the screening process before you are enrolled into the study and receive the investigational study drug. Study drug can be either the investigational medicine or placebo. Not all individuals will qualify to participate in the research.

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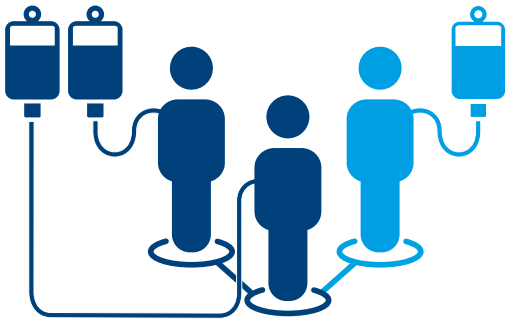
What can I expect if I join the study?

If you qualify and choose to join the study and sign the Informed Consent Form, you will be asked to attend multiple screening visits with the study doctor. At these visits, you will have some health checks to determine if you are a good match for continuing in the study.

- If you are eligible, you will receive the study drug once every month for up to 4.5 years. Depending on when you enter the study, you may be in the study for 3 years or less. You will visit the study doctor or study team every 4 weeks.
- You will be assigned by chance to receive either the investigational medicine or the placebo (which contains no active drug). There is a 2-in-3 chance of receiving the investigational medicine and a 1-in-3 chance of receiving the placebo.



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- Neither you, your study partner, nor the study team will know which study drug you receive.
- The study drug is given by intravenous (IV) infusion, which means it is given directly into a vein in your arm. It will take about 1 hour to give you the study drug. The study team will observe you during and after the infusion to monitor your health.
- People who are eligible to take part will receive study-related medical care and the study drug at no cost. The study will not pay for other medical care or current medication(s) needed to support your daily health care routine.