

What else should you know about the study?

If you are already receiving standard treatments for Alzheimer's disease, in most cases these can be continued during the study.

There is no guarantee that the study drug will improve your symptoms.

Throughout the study, your health will be carefully monitored to help us to know whether remaining in the study is appropriate for you.

The study treatment will be stopped if you or the study doctor have any concerns, or if you change your mind about being in the study.

The study drug and all study-related care will be provided free of charge.

You may be compensated for time and travel.

Interested?

If you think you might like to join the AMARANTH Study, please contact us. We can tell you more about it and explain what participating would mean for you. We will talk through the potential benefits and risks of being involved in the study, before you make your decision about joining.

We will also carry out several medical checks to see whether you are right for the study, and the study is right for you.

Who can join the AMARANTH Study?

To join this study you must:

- ◆ Be between 55 and 85 years old
- ◆ Have either:
 - Experienced gradual and progressive change in memory function over more than 6 months (the study team will assess whether this is due to Alzheimer's disease)
 - Or been diagnosed with mild Alzheimer's disease or mild cognitive impairment
- ◆ Have a friend, relative or caregiver who would be willing to be your study partner throughout the study.

If you would like to learn more about the AMARANTH Study, please contact us at:

Name: Yahdinah Alvarez

Tel. No.: 941-256-8018 ext. 355

Study site: Roskamp Institute

Contacting us does not mean you have to join the study.

216846 USA Recruitment 20140925 Patient Brochure English 2.0

Have you noticed that your memory isn't quite as it used to be?

Are you becoming increasingly forgetful?

Could you have early Alzheimer's disease?



What is Alzheimer's disease? And how do you know if you have it?

As we get older, most of us become more forgetful. Keys go missing, people's names evade us, memories fade.

But if you find that forgetfulness is becoming a problem for you, people comment on your memory loss, or you have difficulty planning or problem solving, these could be early signs of Alzheimer's disease.

Alzheimer's disease is very common – increasingly so the older you are. It affects 1 in 1,400 people aged 40-64 years, 1 in 100 people aged 65–69 years, 1 in 25 of people in their 70s and 1 in 6 people aged 80 years or over.¹

Alzheimer's disease is a type of dementia – which means memory loss and difficulties thinking, problem-solving, and communicating.

Dementia develops due to changes in the structure and chemistry of the brain that affect its ability to function properly when performing certain 'mental' activities. This is known as cognitive impairment.

Whilst there is currently no cure for Alzheimer's disease, there are treatments available that can alleviate symptoms and slow down their progression in some people.

Reference:
1. www.alzheimers.org.uk

Searching for a way to slow the decline

A small number of treatments for Alzheimer's disease are available that can help improve the symptoms of dementia, but these are only useful in the short term. Researchers are trying to find a treatment that can slow or stop the disease process in people with Alzheimer's disease to preserve memory and mental functioning.

Clinical studies are an important part of this research, as they allow scientists to understand which new drug discoveries might be useful for patients.

The AMARANTH Study

A new clinical research study in early Alzheimer's disease – known as the AMARANTH Study – is underway and we are looking for people who would like to participate.

The study will examine an investigational drug that may have some effect on the brain changes associated with Alzheimer's disease. The purpose of the study is to find out whether this investigational drug can influence the decline in memory and mental functioning. 'Investigational' means that the drug has not been approved for clinical use, and is still being evaluated in clinical studies.

The AMARANTH Study involves more than 1500 participants from around 175 study centers like our own, in 15 countries worldwide.

What does joining involve?

The study will last for approximately two years (about 8 weeks to see if you qualify, plus 2 years of treatment, then 4-6 weeks of follow-up).

The study treatment will be a tablet, to be taken once a day. The tablet will contain either lower-dose investigational drug, higher-dose investigational drug or a placebo, depending on which group you are assigned to. A placebo tablet is one that contains no active medication.

As is normal with clinical studies of this type, your group will be chosen randomly, and neither you, nor the study doctor will not know which group you belong to. However, if it is medically necessary to find out, the study doctor can do so quickly. There will be a 2 in 3 chance that you will receive the investigational drug.

You will need a study partner. This person needs to be someone who you are in regular contact with, will go with you to clinic visits and can help the study team to notice any changes in your mental functioning.

If you join the study you and your study partner will be asked to attend around 17 clinic visits and 4 telephone calls, during which we will assess your health with some standard medical tests and questionnaires. We will also ask you about any side effects you may experience. These visits will be every 1-3 weeks for the first two months, and then every 6-7 weeks throughout the course of the study (or throughout the treatment period).