

The DAYBREAK-ALZ Study

The DAYBREAK-ALZ Study is a clinical research study in mild Alzheimer's disease. We are looking for people who would like to participate.

The study will examine an oral investigational medication that may have some effect on the brain changes associated with Alzheimer's disease. The study is designed to find out whether this investigational medication (or "study medication") can slow down the decline in memory and mental functioning. "Investigational" means that the medication is still being evaluated in clinical studies, and has not yet been approved for use by doctors in their everyday practice.

The DAYBREAK-ALZ study will include approximately 1,900 participants from around the globe.

Interested?

If you think you might like to join the DAYBREAK-ALZ Study or you would like to learn more, 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 DAYBREAK-ALZ Study?

To join the study you must:

- Be between 55 and 85 years old
- Have experienced a gradual loss of memory over the last 6 months (the study team will assess whether this is due to Alzheimer's disease)

OR

- Have been diagnosed with mild Alzheimer's disease
- Have a close friend, relative or partner who would be willing to be your study partner throughout the study

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

Name: _____

Tel. No: _____

Study Site: _____

CONTACTING US DOES NOT MEAN YOU HAVE TO JOIN THE STUDY.

DAYBREAK-ALZ Patient Q&A fold_V2_UK(EN)_02September2016

WHERE WAS I GOING ?



DAYBREAK-ALZ

Mild Alzheimer's disease Clinical Research Study

Have you noticed that your memory is getting worse?

Are you having difficulty with planning or problem-solving?

Could it be mild Alzheimer's disease?

This might be for you.

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, we can't remember names easily, 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, it affects one in 1,400 who are age 40-64 years, one in 100 people age 65-69 years, one in 25 of people in their 70s, and one in 6 of people age 80 years or older.¹

Symptoms of Alzheimer's disease include memory loss, difficulties thinking, problem-solving and communicating. Alzheimer's disease 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.

Reference: 1. www.alzheimers.org.uk

Searching for a way to slow the decline

There is currently no cure for Alzheimer's disease. However, some treatments for Alzheimer's disease are available that can help improve symptoms in the short term. Researchers are trying to find a treatment that can slow or stop Alzheimer's disease.

Clinical studies are an important part of this research. They allow scientists to understand which new medication discoveries could be useful for patients.

What does joining involve?

The study will last for around three years – 8 weeks to see if you qualify, plus 3 years of treatment, then 4 weeks of follow-up.

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

You will be assigned at random to one of the study groups. Neither you nor the study doctor will know which group you've been assigned to. There is a 2 in 3 chance that you will receive the study medication. If it is necessary to find out which group you've been assigned to, the study doctor can do so quickly.

You will need a study partner. This person needs to be someone who you are in regular contact with, who will go with you to study appointments, and who 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 29 appointments. During these appointments, we will assess your health, thinking and memory with some standard medical tests and questionnaires. We will also ask you about any side effects you may experience. These appointments will be every 3 weeks for the first few visits and then every 7 weeks until the end of the study.

What else should you know about the study?

If you are already receiving treatment for Alzheimer's disease, it may be possible to continue taking them. The study team will let you know.

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

Your safety is our first priority. Throughout the study, your health will be carefully monitored at all appointments.

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

You may be compensated for time and travel.