

INFORMATION LEAFLET FOR POTENTIAL PARTICIPANTS

WHAT COMES NEXT

**EARLY OR MILD ALZHEIMER'S DISEASE?
COULD THE GRADUATE I CLINICAL STUDY
BE THE NEXT STEP?**

Could *GRADUATE I* be your next step?

If you have just been diagnosed with Alzheimer's disease, or think you might have early signs of the condition, it may be difficult to think about what comes next. But thinking about your future and how to make it better is exactly what researchers around the world are doing – right at this moment, in fact.

For example, we're currently looking for people to join a new clinical study called *GRADUATE I*. The study will assess how safe and effective an investigational drug is at slowing the progression of early (also known as 'prodromal') or mild Alzheimer's disease. And we are looking for people like you to take part.

This leaflet will tell you about the study and help you decide if it could be the right next step for you. It contains a lot of information, so please don't feel that you have to read it all at one time. You may also wish to discuss it with your family, friends or doctor.

What is a clinical study?

Clinical studies (also known as 'clinical trials') are research studies that are designed to help us find:

- Potential new medications
- New versions of medications already being used
- New uses for medications already being used

Participant safety is the top priority of every study. In fact, governments have strict rules to protect the safety and privacy of study volunteers. By law, participants must be told about all the risks and benefits of participation. This is called the 'informed consent' process.

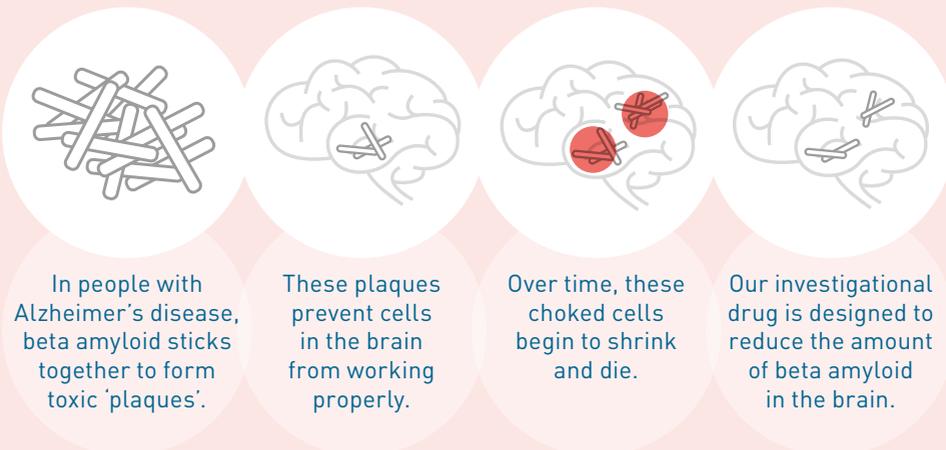
As part of this process, you will be asked to read and sign an informed consent form (ICF) that contains a detailed explanation of the study. You may want to discuss this form with your loved one, alongside your family and friends, if you want to take part.

Why is GRADUATE I important?

There are currently no approved medications that can slow or stop the progression of Alzheimer's disease – only medications that can temporarily lessen secondary symptoms (like memory loss and anxiety) in some people with more advanced Alzheimer's disease.

However, in recent years scientists have made some important discoveries. For example, it is now believed that one of the main features of Alzheimer's disease is the build-up of a certain protein in the brain called beta amyloid – the target of our investigational drug.

How we believe our investigational drug may work



Are you and your loved one a good fit for this study?

If you're interested in taking part in the GRADUATE I study, you will be assessed carefully by the study team to confirm if the study is right for you. You may be able to take part if you:

- Are 50-90 years old
- Have mild Alzheimer's disease or memory problems that may be the early symptoms of Alzheimer's disease
- Have someone you see frequently who will be your Study Partner and can:
 - Attend clinic visits with you when necessary
 - Be available to answer questions about your symptoms and any changes they may notice
 - Provide accurate information about how you are feeling

What's involved in participating?

The total length of the GRADUATE I study is 3 years, excluding participation in an optional extension study. An outline of the GRADUATE I study design follows.

Screening period (Up to 12 weeks)

We will assess your suitability to take part.



Dosing period (2 years)

Half of the participants will receive the investigational drug. The other half will receive a placebo*.

These will be given as subcutaneous (under the skin) injections at a study clinic or home. Injections will take place once every 4 weeks for at least the first 9 months and every 2 weeks thereafter (up to 43 injections in total).



Long-term follow-up (1 year)

We will ask you back for 2 follow-up visits so we can look for any lasting effects.

or

Optional long-term extension study (2 years)

All eligible participants will receive the investigational drug (even those that previously were assigned to the placebo group).

**A placebo is a dummy drug that contains no active ingredients. We use a placebo to help us confirm that any changes we see are due to the investigational drug. Neither you nor the study team will know which group you are in. But the study doctor can find out in case of emergency.*

What happens at study visits

During the study, you will need to visit a study clinic approximately every 2 to 4 weeks so that the study team can administer the study drug and monitor your health and condition. Health assessments will vary between visits, but may include:



Blood tests



Heart checks
(electrocardiograms; ECGs)



Brain imaging
(magnetic resonance imaging scans; MRIs)



Questionnaires

To help us learn more about how the investigational drug affects beta amyloid levels, we will also track the amount of the protein in the body. For example, to measure the amount in the brain, we will carry out a special kind of brain scan called a positron emission tomography (PET) scan. In some participants, we may instead measure the amount of beta amyloid in the fluid that protects the brain and spinal cord. To do this, we take a sample by inserting a needle into the lower back. This standard medical procedure is called a 'lumbar puncture'.

PLEASE NOTE

If you take part in the GRADUATE I study, you'll be given a detailed Study Guide booklet that provides full details of what to expect at each visit.

WHAT COMES NEXT

Taking part in a clinical study is a personal decision and you don't have to take part if you don't want to. It's also important to know that if you start the study and then change your mind, you can leave at any time without any impact on your usual healthcare.

Of course, we understand that when Alzheimer's disease enters our lives, it can be difficult to think ahead. So please take your time deciding. And remember: taking part in a clinical study could be a way for you to help others in a similar position and potentially shape your future care.

If you think you may be interested in taking part, or would like more information, please contact the GRADUATE I study team – they will be more than happy to help. Alternatively, visit our website today to learn more.

STUDY TEAM CONTACT DETAILS:

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