

Welcome to Together

a study about memory loss

We would like to thank you for your interest in the Together study.

The study is part of a global effort to find better choices for treatment in the future for people with early memory loss and for those with early Alzheimer's disease. This study may not directly benefit you medically, but we hope you will find that taking part can be a positive experience. Please note that the information that the research team learns from this study may directly impact the development of future medications.

Introduction:

- The purpose of this brochure is to summarise what will happen during the Together study. You can share this brochure with family and friends if they have questions
- Remember that any questions you may have about the study are important to us. The study team wants to hear every single one of them!



Why do clinical studies take place?

Clinical studies of investigational medications are conducted for all types of conditions. The intention of each study is to find out whether an investigational medicine is well tolerated and effective enough to be made widely available to the public.

What does being in the Together study involve?

Together has two parts. Part 1 is “placebo-controlled”, meaning that:

- You will be randomly allocated to 1 of 3 treatment groups by a computer
- One third will receive a lower dose of the **active study drug by infusion** throughout the study
- One third will receive a higher dose of the **active study drug by infusion** throughout the study
- One third will receive a water-based solution by infusion. This is called a “**placebo**” infusion. Placebo is a technical word that describes a study drug that has no active ingredients in it



It is completely down to chance, like tossing a coin, who goes into which group.

Part 1 of Together is also a “blinded” study, meaning that:

- Neither you nor your study doctor will know what treatment you are receiving during Part 1 of the study

Part 2 of Together is an “open-label extension”:

- This means that **everyone** receives the investigational medication

How long does the study last?

- Part 1 takes about 80 weeks
- Part 2 is an additional 44 weeks after Part 1, followed by 20 weeks of follow-up visits
- There are also important follow-up visits to attend whether you end the study at Part 1 or Part 2
- Most of your visits will take 5 to 6 hours, some may take longer. We will try to make your stay as comfortable as possible



Why is a placebo necessary?

We need to be able to assess people’s symptoms before and after they have taken the active study drug. This is the only way to be certain that any health changes or side effects are caused purely by the investigational drug and not by anything else such as, for example, hoping to feel an improvement so thinking that you have noticed one.

The only way that we can be certain that the drug is the reason for any change in your health is if:

- You do not know if you are on the active drug or the placebo
- Your doctors do not know if you are on the active drug or the placebo

A placebo-controlled study like Together can therefore establish whether the investigational drug is responsible for any changes to your symptoms.

What to expect over the next year and beyond...



Screening time, plus Part 1, Part 2 and follow-up time adds up to around 3 years.



One third of participants in Part 1 will receive a placebo, NOT the active study drug. However, EVERYONE who completes Part 1 and goes into Part 2 WILL receive the active study drug, the investigational medication.



Many of the assessments that take place during the screening visit will be repeated at further visits. See below for details. This is a summary, so please ask for additional explanations if you would like more. If you decide to take part in the study, we will support you with detailed information about your visits.

Assessments at clinic visits include...



Questions: Surveys and memory tests, which can become quite tiring. We ask people to let us know if they ever need a break.



Measurements: For example, weight and height, blood pressure and heart rate.



Blood and urine tests: In order to check how your body is reacting to being in the study.



Infusions of study drug: These infusions usually take 2 hours (the maximum duration is 4 hours) and happen at 32 visits. Infusions do not usually hurt, but you may want to bring a book!



Brain scan (MRI): This is painless. Basically, you lie still in a giant camera, which can be harder to do than it sounds!



PET scan: This is another giant camera situation. With a PET scan though, we need to inject a liquid into your body first. The liquid we inject is called a radiotracer. You will get more information about this. There are 4 visits where a PET scan happens.



Lumbar puncture: This is an optional procedure where, using local anaesthetic, a hollow needle is inserted into your back, in between two of your vertebrae, and some spinal fluid is removed. We then analyse the fluid to learn more about the impact of the study medication.



Here are your responsibilities...

Please stay in touch! It is really helpful to let us know whenever you have any concerns or questions. For example, if you are worried about attending a visit, give us a call! If you have any questions about your health, just pick up the phone and let us know.

Remember, there is no obligation to stay in the study. We just ask that you let us know if you are thinking of leaving the study, so that we can ensure the healthcare support you need is in place.

And here is our commitment to you...

We will listen to you and we will always put your medical needs first. PLEASE remember that we are here for you. Let us know how we can support you.

The most important people in our team are our study participants. We would like to thank all the people who give time with their families to make research happen.

Without our participants, science simply could not progress.

My Together Team

