**WN42444 Summary Participant Information Sheet (PIS)**

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| A PHASE III STUDY TO EVALUATE GANTENERUMAB IN PARTICIPANTS AT RISK FOR OR AT THE EARLIEST STATES OF ALZHEIMER’S DISEASE | |
| This study, WN42444 is comparing the effects, good or bad, of gantenerumab versus placebo in people who are at risk of developing or in the earliest stages of Alzheimer’s disease. A ‘placebo’ medicine looks the same as the study treatment (in this case gantenerumab) but does not contain any active ingredients.  This study includes people who are 60-80 years of age (inclusive) who have a certain level of brain function (be cognitively unimpaired) and higher levels of amyloid protein in the brain. People who have higher brain amyloid levels may be at risk for or at the earliest stages of Alzheimer’s disease.  Gantenerumab is a manmade antibody (an antibody is a type of protein that is normally made by the immune system to help defend the body from infection or cancer) that attaches to amyloid in the brain and triggers the immune system to remove it. It is thought that removing brain amyloid may slow down the disease process that underlies Alzheimer’s disease. | |
| |  | | --- | | **IMPORTANT**  **THINGS TO KNOW** | | You and your carer will be reimbursed for any direct costs as a result of taking part in this study  You do not have to take part and you can stop at any time without affecting your medical care in any way.  Your privacy is very important, your information and samples will be kept confidential at all times to ensure your health information is safe and protected.  If you are interested in this study, you will be given the Main Participant Information Sheet, this covers all parts of the study in more detail to help you decide if you would like to take part. | | **What is the purpose of the study?**  The purpose of this study is to compare the effects, good or bad, of an investigational drug (gantenerumab) with those of placebo in participants who are at risk for or at the earliest stages of Alzheimer’s disease. Your doctor and/or nurse thinks you may meet the study criteria and may benefit from treatment you could get as part of this study.  **What will happen in the study?**  Screening: You will need to complete some screening tests if you agree to take part in the study; this is to check you meet the criteria to take part. These include physical tests and memory tests that are described in the main participant information sheet. Screening for this study can take up to 17 weeks.  Treatment Period: If you meet the criteria and agree to take part in the study, you will complete further tests and receive study treatment. Study treatment is an injection under the skin of gantenerumab or placebo, which one you receive will be decided at random (like flipping a coin) when you start the study and you will not know which one.  For the first 9 months (approximately) you will receive increasing volumes of injection, this is to reach the target dose of study treatment. You will be carefully monitored when you are being given the study drug and for some time afterwards to check for any reaction to the study drug. When you have reached the target dose of study treatment you will be able to choose if you have one injection once every week, or two injections once every 2 weeks. You may also be able to choose to have the study treatment at home by self-administration or by a mobile nurse.  Study Duration: Your total time in the study will be approximately 4 years and 9 months.  **Are there any risks?**  There are always potential risks with taking part in any clinical trial. Up to now, approximately 2500 patients have received treatment with gantenerumab, and some side effects are known. These potential side effects are described in detail in the main participant information sheet.  We do not know what the risks might be to an unborn child. You cannot participate in the trial if you are pregnant, intend to become pregnant or are unwilling to use effective contraception during the study. |
| If you have general questions about dementia or want to know more about dementia research and how you and your loved ones can get involved, the Alzheimer’s Research UK, Dementia Research Infoline can help.  **You can call them** on 0300 111 5 111 between 9.00-5.00pm Monday to Friday (excluding bank holidays). Calls are charged at the same rate as 01 or 02 number and should be included in free call packages.  **You can email them** at [infoline@alzheimersresearchuk.org](mailto:infoline@alzheimersresearchuk.org)  **You can write to them** at Dementia Research Infoline, Alzheimer’s Research UK, 3 Riverside, Granta Park, Cambridge, CB21 6AD  <https://www.alzheimersresearchuk.org/about-us/contact-us/dementia-research-infoline/>    Join Dementia Research is a national service that allows members of the public to register their interest in taking part in dementia research studies. The service is not a research study itself, but matches interested volunteers with researchers who are seeking participants for their studies.  The goal is to make it possible for anyone who wants to be involved in dementia research to get the chance to do so.  <https://www.joindementiaresearch.nihr.ac.uk/>  You can view a video further explaining the study by following this QR code (a type of barcode that can be read by digital devices, i.e. the camera on your phone):  C:\Users\fielderm\Downloads\Skyline Video.png  There is also a website link to this video:  <https://tinyurl.com/2nfcvr7p>  **Thank you for taking the time to read this Summary Information** | |