Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

SKYLINE STUDY

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SKYLINE study

1. Study Information	
Name of the study	A study to evaluate the efficacy and safety of gantenerumab in participants at risk for or at the earliest stages of Alzheimer's disease
Study sponsor	Hoffmann-La Roche
Disease	At risk for or at the earliest stages of Alzheimer's disease
Phase	Phase III

2. Information about the drug that will be tested in the study	
Name of drug	Gantenerumab
Administration	The drug will be administered via a subcutaneous injection (an injection under the skin).
Is the drug already on the market for another medical condition?	No
Will all participants receive the same drug?	Participants will be selected by chance to receive one of the following options: • A subcutaneous injection of gantenerumab • A subcutaneous injection of placebo (also called a dummy treatment which is an inactive substance identical in appearance to the drug being tested with no active therapeutic effect). Neither the participant nor their doctor will know if the person is receiving the investigational drug or the placebo.

3. Information about participating in the trial	
What are the researchers trying to find out?	• The purpose of the study is to evaluate the efficacy and safety of gantenerumab in people at risk for or at the earlier stages of Alzheimer's disease.
How long will the treatment last?	• The treatment period will be split into two parts • Participants will be asked to choose how they would like to be given treatment in Part 2: one injection every week or two

	injections once every two weeks. This will also affect how participants are given treatment in Part 1 • In Part 1, participants will be given either gantenerumab or placebo once every four weeks for at least six months, then one injection every two weeks for three months (if participants prefer one injection every week in Part 2) or two injections once every four weeks for three months (if participants prefer two injections once every two weeks in Part 2). The dose of the drug will be gradually increased during the time of the Part 1 • In Part 2, participants will be given either gantenerumab or placebo every week or two injections once every two weeks, until the end of the four-year treatment period. The Part 2 refers to a maintenance phase where participants will receive the target dose of the drug (the dose believed to have the best effect) • The total duration of the study is 4 years • During the study, participants will have regular clinic visits every six months.
What your involvement will entail?	• During the study, participants will be asked to complete a test that will assess their episodic memory, timed executive function, and global cognition (this test is called Preclinical Alzheimer's Cognitive Composite-5 (PACC-5)) • Complete tests that will assess their cognition, memory, behaviour and activities of daily living (i.e. tests like A-IADL-Q-SV, CFIa, CDR-SB) • Complete some laboratory tests to evaluate the emergent adverse effects (unfavourable signs, symptoms or diseases temporally associated with the use of the drug tested in the study)

	• During the study, participants will have to undergo brain scan (MRI, PET) or CSF examination (spinal tap). Further information on the number of visits can be obtained from the study team.

4. Who can participate in this study?	
Who can participate in the study?	To take part in the study, participants must: • Be 60 to 80 years old • Have a score of 0 in the Clinical Dementia Rating-Global Score (CDR-GS) and a score above 80 in the Repeatable Battery for the Assessment of Neuropsychological Status Delayed Memory Index (RBANS DMI). This would suggest that the person has no impairment in their memory • Have evidence of abnormal accumulation of amyloid in their brain (as per results of CSF examination (spinal tap) or of PET scan) • Have a study partner who has a sufficient contact with the participant, is willing to participate in study procedures throughout the study duration • Adequate visual and auditory acuity, sufficient to perform neuropsychological testing (eye glasses and hearing aids are permitted) • Agreed not to participate in other interventional research studies for the duration of this study • For women of childbearing potential: agreement to remain abstinent or use contraceptive methods.
Who cannot participate in the study?	Exclusion criteria include: • Any evidence of a neurological or neurodegenerative condition that may lead to cognitive impairment other than

	Alzheimer's disease • Clinical diagnosis of mild cognitive impairment, prodromal Alzheimer's disease, or any form of dementia • History of evident vascular disease that may affect cognition • A disease or medical condition that may interfere with the study assessments and will make the participant unsuitable for participation in or completion of the trial procedures (i.e. ischemic stroke, trauma, major depression, schizophrenia) • At risk of suicide in the opinion of the investigator • History of alcohol and/or substance abuse or dependence • Unstable or clinically significant cardiovascular, kidney or liver disease or uncontrolled hypertension • History of HIV infection, or hepatitis B or hepatitis C virus infection • Current COVID-19 infection • Contradictions to brain scans (MRI, PET) or CSF examination (spinal tap). The above list is not exhaustive. It includes the most common conditions and diseases that might exclude people from the study.

5. Where and when will the study be conducted?	
European countries that are involved in the trial (active)	• Italy • Poland • Spain

	• Sweden
European countries that will be involved in the trial (planned)	• Belgium • Germany • Ireland • France • Netherlands • UK
Estimated start date of recruitment	May 2022

6. Information for your doctor			
EudraCT Number:	2021-001184-25	**Clinicaltrials.gov identifier**	NCT05256134
Study contact information	global-roche-genentech-trials@gene.com		
Link to full text	https://clinicaltrials.gov/ct2/show/NCT05256134		
Study website	https://forpatients.roche.com/en/trials/neurodegenerative-disorder/ad/a-study-to-evaluate-the-efficacy-and-safety-of-gantener-84528.html		

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on July 2022.
- ✓ This document has been reviewed by the pharmaceutical company running this trial.
- ✓ This document has been reviewed by a member of the European Working Group of People with Dementia.