Alzheimer Europe

Making dementia a priority:
changing perceptions, practice and policy.

CLINICAL TRIALS WATCH

ACCESIBLE EASY READ INFORMATION ON:

GRADUATE 1 & GRADUATE 2 STUDIES

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GRADUATE 1 & GRADUATE 2 studies

1. Studies Information	
Name of the studies	A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Efficacy, and Safety Study of Gantenerumab in Patients With Early Alzheimer's Disease
Studies sponsor	Hoffmann- La Roche
Disease	Prodromal to mild Alzheimer's disease
Phase	Phase III

2. Information about the drug that will be tested in the studies	
Name of drug	Gantenerumab
Administration	• The drug will be administered via a subcutaneous injection (an injection under the skin) every month for the first 9 months and then every 2 weeks.
Is the drug already on the market for another medical condition?	No
Will all participants receive the same drug?	Participants will be selected at random to either receive one of the following options: • A subcutaneous injection of gantenerumab OR • A subcutaneous injection of placebo (a substance identical in appearance to the drug being tested with no active therapeutic effect). Neither the participant nor his/her doctor will know if the person is receiving the investigational drug or the placebo.

3. Information about participating in the trials	
What are the researchers trying to find out?	• The researchers aim to evaluate the efficacy and safety of gantenerumab in people with early Alzheimer's disease.
How long will the treatment last?	• 104 weeks (around 2 years)
What will your involvement entail?	• Participants will have to undergo brain scan (PET) or CSF examination (spinal tap) to see if they have amyloid pathology in their brain • Complete a test that will assess their memory, orientation, judgment and problem solving, personal care and community affairs (this is a test called CDR). The study partner will also be asked to answer these questions • During the study, participants will be asked to complete other tests that will assess their memory, language, functioning, behaviour, quality of life and other health-related questionnaires (i.e. tests or scales like MMSE, ADAS-Cog…) • Participants will have to undergo regular brain scans (MRI) to ensure safety. Further information on the procedures, tests and number of visits can be obtained from the study team.

4. Who can participate in these studies?

Who can participate in these studies?	To take part in these studies, the person must: • Be between 50 and 90 years old • Have a study partner who has a sufficient contact with the participant, is willing to participate in study procedures throughout the study duration • Have evidence of abnormal accumulation of amyloid in their brain (as per results of CSF examination (spinal tap) or of PET scan) • Have an impairment in their memory at screening visit • Have a score between 22-30 points in the MMSE test (a test about a range of everyday mental skills) and between 0.5 and 1.0 in the Clinical Dementia Rating-Global Score (CDR-GS). This would suggest that the person has an impairment that is still at an early stage • Meet the clinical criteria for probable Alzheimer's dementia or prodromal Alzheimer's disease of the National Institute on Aging/Alzheimer's Association (NIAAA) • If the person is taking an approved anti-dementia medication (i.e. donepezil, rivastigmine, galantamine or memantine) the dosing regimen must have been stable for at least 3 month prior to the screening visit.
Who cannot participate in these studies?	People cannot take part in these studies if they have or have experienced: • Any evidence of a condition other than Alzheimer's disease that may affect cognition (e.g. other type of dementia, stroke, brain damage, autoimmune disorders (e.g. multiple sclerosis) or infections with neurological involvement) • History of evident vascular disease that may affect cognition

	• History of major psychiatric illness such as schizophrenia or major depression (if not considered in remission) • At risk of suicide in the opinion of the investigator • Contraindication to brain scans (MRI or PET) • Unstable or clinically significant cardiovascular, kidney or liver disease or uncontrolled hypertension • Alcohol or drug abuse within the past 2 years 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 studies be conducted?

European countries involved in these trials	**GRADUATE 1**	**GRADUATE 2**
Belgium		X
Croatia		X
Denmark		X
Finland		X
France	X	
Germany	X	
Hungary	X	
Italy	X	
Lithuania	X	
Netherlands		X
Poland		X
Portugal		X
Russia	X	
Spain	X	X
Sweden		X
Turkey		X
United Kingdom		X
Estimated start date of recruitment	July 2018	July 2018

6. Information for your doctor		
	GRADUATE 1	**GRADUATE 2**
EudraCT Number:	2017-001364-38	2017-001365-24
Clinicaltrials.gov identifier	NCT03444870	NCT03443973
Link to full text	https://clinicaltrials.gov/ct2/show/study/NCT03444870	https://clinicaltrials.gov/ct2/show/study/NCT03443973
Contact information for both studies	global-roche-genentech-trials@gene.com	

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on May 2020.
- ✓ The pharmaceutical company running these trials (Hoffmann- La Roche) has reviewed this document.
- ✓ This document has been reviewed by a member of the European Working Group of People with Dementia.