Alzheimer Europe

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

CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

Autonomy STUDY

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Autonomy study

1. Study Information	
Name of the study	A study of JNJ-63733657 in participants with early Alzheimer's disease
Study sponsor	Janssen Research & Development
Disease	Early Alzheimer's disease
Phase	Phase II

2. Information about the drug that will be tested in the study	
Name of drug	JNJ-63733657
Administration	The drug will be administered via an intravenous infusion (an injection into the vein) every four weeks.
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: • An intravenous injection of JNJ-63733657 (low dose) • An intravenous injection of JNJ-63733657 (medium dose) • An intravenous injection of placebo (inactive substance identical in appearance to the drug being tested). 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 check how safe and effective the investigational medicine (JNJ-63733657), an anti-tau monoclonal antibody, is in participants with early Alzheimer's disease.
How long will the treatment last?	• The study consists of a screening period (3 months), a double-blind treatment period (up to 4.5 years) and a follow-up period (3 months).

	• The maximum treatment duration is up to 232 weeks (4.5 years), but most people are in the study for 3 years or less.
What your involvement will entail?	• During the study, participants will need to complete some tests to evaluate their cognition, behaviour, function and activities of daily living (e.g. ADAS-Cog 13, RBANS, NPI). • Complete a test that will assess memory, orientation, judgment and problem solving, personal care and community affairs • Participants will have multiple pictures taken of their brain called a Magnetic Resonance Imaging (MRI) and Tau Positron emission tomography (PET) scan • Do physical examination and an electrocardiogram (ECG), which isa test that records the electrical activity of the heart. • Complete some laboratory tests and neurological examination to evaluate the emergent adverse events (unfavourable signs, symptoms or diseases temporally associated with the use of the drug tested in the study). 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 55 to 80 years old • Complete at least 5 years of school and are able to read and write • Experiencing a gradual decline in cognitive abilities (e.g. memory, problem-solving skills, and ability to pay attention and think clearly over at least the past 6 months or have been diagnosed with early Alzheimer's disease (also known

	as prodromal Alzheimer's disease or mild Alzheimer's disease dementia) • Have a close reliable friend, relative, or spouse (study partner) who spends at least 10 hours every week with the participant, and is willing to participate in study procedures throughout the study duration.
Who cannot participate in the study?	Exclusion criteria include: • Participants who have dementia but is not caused by Alzheimer's disease • Live in a nursing facility • Had a problem with alcohol or recreational drugs in the past 5 years The above list is not exhaustive. It includes the most common conditions and diseases that might exclude people from the study. The study doctor or study team will check additional criteria during the screening process before you are enrolled in the study.

5. Where and when will the study be conducted?	
European country that are involved in the trial (active)	• Belgium • France • Netherlands • Spain • Sweden
European countrY that will be involved in the trial (planned)	• United Kingdom
Estimated start date of recruitment	April 2021

6. Information for your doctor			
EudraCT Number:	2020-000116-30	**Clinicaltrials.gov identifier**	NCT04619420
Study contact information	JNJ.CT@sylogent.com		
Link to full text	https://clinicaltrials.gov/ct2/show/NCT04619420		

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on January 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.