Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

Retain STUDY

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Retain study

1. Study Information	
Name of the study	A Study of JNJ-64042056 in participants with preclinical Alzheimer's disease
Study sponsor	Janssen Pharmaceutica N.V., Belgium
Disease	Preclinical Alzheimer's disease
Phase	Phase II

2. Information about the drug that will be tested in the study	
Name of drug	JNJ-64042056
Administration	The drug will be administered intramuscularly (by injection in the upper arm) at the following timepoints for a total of 9 injections: • Day 1 • 2 months • 6 months • 6 additional injections occurring every 6 months.
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: • Intramuscular injection of JNJ-64042056 • Intramuscular 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 JNJ-64042056 in people with preclinical Alzheimer's disease (people who are cognitively healthy and have tau biomarkers indicating an increased risk of developing dementia in the future).

How long will the treatment last?	• The study consists of a pre-screening period (4 weeks or more, depending on the availability of the blood results), a screening period (up to 13 weeks) following by the treatment period (up to 4 years). Participants who complete the treatment period will then enter a safety follow-up period (14 days).
What will your involvement entail?	• During the study, participants will be asked to complete tests that will assess their cognition, behaviour, function and activities of daily living (e.g. MMSE, PACC-5, CDR, ADCS-ADL-PI) • Participants will have multiple pictures taken of their brain called a Magnetic Resonance Imaging (MRI) and Tau Positron emission tomography (PET) scan • Complete physical examinations and electrocardiograms (ECG), which is a test that records the electrical activity of the heart • Complete laboratory tests (blood and urine) and neurological examinations 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 procedures, tests and 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 between 55 and 75 years old • Have elevated brain tau pathology (observed in tau PET scan). Only people within a specific range of Tau will be able to join the study • Have a score of 0 in the Clinical Dementia Rating (CDR) global score and greater than or equal to 27 in the MMSE score. This would suggest that the person has no

	impairment in his/her memory • Women of non-childbearing potential (surgically sterilised or post-menopausal) • Have a study partner who has regular contact with the participant, is willing to participate in study procedures throughout the study duration.
Who cannot participate in the study?	Exclusion criteria include: • Diagnosis of Mild Cognitive Impairment or dementia (e.g. Alzheimer's dementia, frontotemporal dementia, Lewy body dementia, vascular dementia) • Vitamin B12 or folate levels below the central laboratory lower limit of normal, unless in the opinion of the investigator it does not require treatment • History of a neurological disease other than preclinical Alzheimer's disease that may interfere with the study assessments (make interpretation of possible new neurological signs or symptoms difficult). 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 involved in the trial (active)	• Belgium • France • Germany • Spain • Sweden • UK

Estimated start date of recruitment	August 2024

6. Information for your doctor			
Clinicaltrials.gov identifier	NCT06544616	**EU CT Number**	2023-505096-68-00
Study contact information	Participate-In-This-Study@its.jnj.com		
Link to full text	https://clinicaltrials.gov/study/NCT06544616 https://euclinicaltrials.eu/search-for-clinical-trials/?lang=en&EUCT=2023-505096-68-00		

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) in November 2025.

- ✓ This document has been reviewed by the pharmaceutical company running this trial.

- ✓ This document has been reviewed by a member of the European Dementia Carers Working Group.