Alzheimer Europe

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

CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

evoke+ STUDY

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evoke+ study

1. Study Information	
Name of the study	evoke+ - A research study investigating Semaglutide in people with early Alzheimer's disease
Study sponsor	Novo Nordisk A/S
Disease	Early Alzheimer's disease
Phase	Phase III

2. Information about the drug that will be tested in the study	
Name of drug	Semaglutide
Administration	The drug will be administered orally once daily.
Is the drug already on the market for another medical condition?	Yes - anti-diabetic medication
Will all participants receive the same drug?	Participants will be selected by chance to receive one of the following options: • An oral dose of semaglutide (dose gradually increased from 3 to 14 mg) • An oral dose 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 safety and efficiency of oral Semaglutide in people with early Alzheimer´s disease.
How long will the treatment last?	• Around 3 years
What your involvement will entail?	• Complete a test that will assess memory, orientation, judgment and problem solving, personal care and community affairs (this is a test called CDR-SB)

	• During the study, participants will be asked to complete tests that will assess their functioning, behaviour and quality of life (i.e. tests like ADCS-ADLMCI and ADAS-Cog) • Participants will be asked to undertake brain scans (MRI or CT) plus either a PET scan or a lumbar puncture (CSF) to see changes in biomarkers in the brain • Participants will also need to complete some other questionnaires to evaluate their cognition, behaviour and function (e.g. NPI, MMSE). 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 85 years old • Have a diagnosis of mild cognitive impairment or mild dementia both of the Alzheimer's type according to the National Institute on Aging/Alzheimer's Association core clinical criteria • Have a score of 0.5 to 1 in the Clinical Dementia Rating-Global Score (CDR) and a score of 22 or above in the MMSE test (a test about your memory). This would suggest that the person has an impairment in their memory that is at a mild stage • Have evidence of abnormal accumulation of amyloid in their brain (PET scan or CSF) • If the person is taking approved symptomatic medication for dementia (i.e. donepezil, rivastigmine, galantamine or

	memantine) the dosing regimen must have been stable for at least three months • Have a study partner who has a sufficient contact with the participant and is willing to participate in study procedures throughout the study duration. • Participants with signs of so-called small vessel disease on top of Alzheimer's Disease can be included
Who cannot participate in the study?	Exclusion criteria include: • Participant who have relevant neurological disorder other than mild cognitive impairment or mild dementia of the Alzheimer's type (i.e. such as Parkinson's disease, Lewy body disease, frontotemporal dementia of any type, Huntington's disease) • Brain scans showing significant abnormality (apart from small vessel changes) • A pregnancy or lactation for female participants. 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 country be involved in the trial (active)	• Austria • Belgium • Bulgaria • Croatia • Czech Republic • Denmark • Finland

	• France • Germany • Greece • Hungary • Ireland • Israel • Italy • Netherlands • Poland • Portugal • Russia • Serbia • Slovakia • Slovenia • Spain • Sweden • Switzerland • Turkey • Ukraine • UK
European countries that will be involved in the trial (planned)	• Romania
Estimated start date of recruitment	May 2021

6. Information for your doctor			
EudraCT Number:	2020-004864-25	**Clinicaltrials.gov identifier**	NCT04777409
Study contact information	clinicaltrials@novonordisk.com		
Link to full text	https://clinicaltrials.gov/ct2/show/NCT04777409		

- ✓ 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.