Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

Semaglutide STUDY

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Semaglutide study

1. Study Information	
Name of the study	A clinical study investigating the effect of semaglutide on the immune system and other biological processes in people with early Alzheimer's disease
Study sponsor	Novo Nordisk A/S
Disease	Alzheimer's disease
Phase	Phase IIIb

2. Information about the drug that will be tested in the study	
Name of drug	Semaglutide
Administration	The study partner will use a pen injector to give the participant an injection into the skin of their stomach, thigh, or upper arm once every week.
Is the drug already on the market for another medical condition?	Yes - semaglutide is a medicine that doctors can prescribe in some countries for the treatment of type 2 diabetes and excess body weight
Will all participants receive the same drug?	Participants will be selected by chance to receive one of the following options: • A subcutaneous injection of semaglutide • 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 (semaglutide) 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 look at the effect of semaglutide on the immune system and other biological processes in people with early Alzheimer's disease to gain further understanding of

	how semaglutide works and may benefit people with early Alzheimer's disease.
How long will the treatment last?	• About 77 weeks • In the first 12 weeks of treatment, participants will either get semaglutide or placebo. In the following 52 weeks of treatment, all participants taking part in the study will get semaglutide.
What your involvement will entail?	Prior to study initiation, participants will have to undergo an MRI brain scan. At the start if the study, participants will be asked to complete a number of tests that will assess memory, orientation, judgment and problem solving, personal care and community affairs using a test called CDR-GS. During the study, participants will be asked to undergo blood sampling and 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 55 to 75 years old • Have a diagnosis of mild cognitive impairment (MCI) or mild dementia of the Alzheimer's type • Have a score of 0.5 or 1 in the Clinical Dementia Rating-Global Score (CDR-GS). This would suggest that the person has an impairment at a mild stage • Have evidence of abnormal accumulation of amyloid in their brain (established by PET scan or CSF lumbar puncture or

	blood sample) • Be treated with acetylcholinesterase inhibitors (approved for the treatment of Alzheimer's disease) and on stable dose for greater than 90 days before screening • Must have a study partner, who is willing to take part in the study and willing to participate in study procedures throughout the study duration (e.g. injecting participant with weekly injections).
Who cannot participate in the study?	Exclusion criteria include: • Brain MRI scan results suggesting clinically significant structural central nervous system (CNS) diseases (e.g. cerebral large-vessel disease, macro-haemorrhage, cerebral vascular malformations, small vessel pathology) • History or evidence of autoimmune diseases such as inflammatory bowel disease, rheumatoid arthritis, lupus, glomerulonephritis, psoriasis • Received a vaccine product 4 weeks prior to screening • Use of any systemic immunomodulating drugs in the last 12 months (e.g. corticosteroids for systemic use, immunostimulants and immunosuppressants). Note that this list is not exhaustive but it rather focuses on the most common conditions and diseases excluding people from the study.

5. Where and when will the study be conducted?	
European countries involved in the trial (active)	• Denmark • Sweden • Switzerland
European country that will be involved in the trial (planned)	• Italy
Estimated start date of recruitment	July 2023

6. Information for your doctor			
EudraCT Number:	2022-003384-24	**Clinicaltrials.gov identifier**	NCT05891496
Study contact information	clinicaltrials@novonordisk.com		
Link to full text	https://clinicaltrials.gov/study/NCT05891496		

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on December 2023.
- ✓ The pharmaceutical company running this trial has reviewed this document.
- ✓ This document has been reviewed by a member of the European Dementia Carers Working Group.