Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

COMMETS STUDY

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COMMETS study

1. Study Information	
Name of the study	Combination of intranasal insulin with oral semaglutide to improve cognition and cerebral blood flow: a feasibility study
Study sponsor	Rutgers, The State University of New Jersey
Disease	Older adults with metabolic syndrome and Mild Cognitive Impairment (MCI)
Phase	Phase II

2. Information about the drug that will be tested in the study	
Name of drug	A combination therapy of intranasal insulin with semaglutide
Administration	Insulin: intranasal administration with a nasal spray (twice per day, 20 seconds each sniff, in each nostril) Semaglutide: oral tablet once daily
Is the drug already on the market for another medical condition?	Insulin is a medication used in the treatment and management of diabetes, including type 1 diabetes, type 2 diabetes and gestational diabetes. Semaglutide is an antidiabetic medication used for the treatment of type 2 diabetes and an anti-obesity medication used for long-term weight management.
Will all participants receive the same drug?	Participants will be selected by chance to receive one of the following options: • An intranasal insulin injection and an oral tablet of semaglutide • An intranasal insulin injection and an oral tablet 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) • An intranasal injection of placebo and an oral tablet of semaglutide • An intranasal injection of placebo and an oral tablet of 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 of intranasal insulin with semaglutide, a combination therapy with strong biological plausibility to benefit impaired cognition through vascular mechanisms, in older adults with metabolic syndrome and MCI, who are enriched for cerebrovascular disease and at high dementia risk. The study will focus on cognitive and biological outcomes.
How long will the treatment last?	• 12 months
What your involvement will entail?	• During the study, participants will be asked to complete some tests that will assess cognitive and functional measures, activities of daily living and physical capacity • To undergo brain scan (e.g. MRI) • To undergo blood tests. 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 60 and 90 years old • Have a diagnosis of MCI (have a MOCA score >20 and a CDR score of 0.5 representing questionable dementia) • Have a diagnosis of metabolic syndrome, requiring abdominal obesity, glucose intolerance and at least one of the following: 1) dyslipidemia (high triglycerides) and low HDL, or 2) elevated blood pressure

	• Fluent in Hebrew • Have a study partner who has a sufficient contact with the participant, is willing to participate in study procedures throughout the study duration.
Who cannot participate in the study?	Exclusion criteria include: • Any type of diabetes • Taking medications that may affect glucose metabolism (i.e. GLP-1RA) • Diagnosis of dementia • A disease or condition that may interfere with the safety, tolerability and/or study assessment including short life expectancy • Contraindications to either insulin or semaglutide • Medications that may affect glucose metabolism such as corticosteroids. 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 involved in the trial	• Israel
Estimated start date of recruitment	January 2024

6. Information for your doctor	
Clinicaltrials.gov identifier	NCT06072963
Study contact information	Iscka Yore, +972-35307262 Iscka.Yore@sheba.health.gov.il Tal Niv, +972-35305406 Tal.Niv@sheba.health.gov.il
Link to full text	https://clinicaltrials.gov/study/NCT06072963

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on June 2024.

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

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