Alzheimer Europe

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

CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

FMD AD STUDY

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FMD AD study

1. Study Information	
Name of the study	Clinical trial of a low protein diet in patients with cognitive impairment
Study sponsor	University of Genova
Disease	Mild Cognitive Impairment or mild Alzheimer's disease
Phase	Phase I/II

2. Information about the dietary supplement that will be tested in the study	
Name of the dietary supplement	Fasting-Mimicking Diet ProlonADTM
Administration	A dietary kit providing the food to eat once a month for five days during 12 consecutive months
Is the dietary supplement already on the market for another medical condition?	No
Will all participants receive the same dietary supplement?	Participants will be selected by chance to receive one of the following options: • The ProlonADTM diet, which is a low-calorie and low-protein diet, providing all the micronutrients necessary to avoid malnutrition • A placebo meal (also called a dummy meal which is a meal identical in appearance to the meal being tested without calories restrictions). 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 feasibility and safety of a 5-day low protein fasting-mimicking diet in people affected by mild cognitive impairment or early Alzheimer's disease.
How long will the treatment last?	• 12 months

What your involvement will entail?	• During the study, participants will be asked to complete some laboratory/biological tests to evaluate the emergent adverse effects (unfavourable signs, symptoms or diseases temporally associated with the use of the drug tested in the study) and key markers in inflammation, oxidative stress and cell aging • Participants will complete various tests that will assess emotional state, activities of daily living, quality of life, cognition and memory (i.e. Barthel Index, CESD-R, QLQ-AD, FCRST, MMSE). 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, all participants must: • Be 50 to 80 years old • Have a Mini-Mental State Examination (MMSE) score between 18 and 23. This would mean that the person has mild cognitive impairment or early Alzheimer's disease • Have a Body Mass Index (BMI) not less than 20 kg/m2
Who cannot participate in the study?	Exclusion criteria include: • Diabetes mellitus • Organ impairment (liver, kidney) • Food allergies to the components of the dietary supplement • Participants who live alone or are not adequately supported by a study partner

	• Other experimental therapies in progress. 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	• Italy
Estimated start date of recruitment	November 2019

6. Information for your doctor	
Clinicaltrials.gov identifier	NCT05480358
Study contact information	Alessio Nencioni +390103538990 alessio.nencioni@unige.it Patrizia Mecocci +390755783839 patrizia.mecocci@unipg.it
Link to full text	https://clinicaltrials.gov/ct2/show/NCT05480358

✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on September 2022.