Alzheimer Europe

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

CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

NorAD STUDY

Alzheimer Europe A.S.B.L. • R.C.S. Luxembourg F2773 • 14, rue Dicks • L-1417 Luxembourg
Tel.: +352-29 79 70 • Fax: +352-29 79 72 • info@alzheimer-europe.org • www.alzheimer-europe.org

NorAD study

1. Study Information	
Name of the study	Randomised Clinical Trial of Noradrenergic Add-on Therapy With Extended-Release Guanfacine in Alzheimer's Disease
Study sponsor	Imperial College London
Disease	People with mild to moderate Alzheimer's disease
Phase	Phase III

2. Information about the drug that will be tested in the study	
Name of drug	Guanfacine
Administration	A tablet taken orally once a day
Is the drug already on the market for another medical condition?	Yes, to treat Attention Deficit Hyperactivity Disorder (ADHD) in children
Will all participants receive the same drug?	Participants will be selected at random to either receive one of the following options: • A tablet of 2 mg of Guanfacine • One placebo tablet (also called a dummy treatment which is an inactive substance identical in appearance to the drug being tested). 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 assess whether a medication called Guanfacine can improve thinking (particularly attention), in people with Alzheimer's disease when given alongside other standard medication that are normally used in this condition (e.g. Donepezil, Rivastigmine or Galantamine).
How long will the treatment last?	• 12 weeks

What your involvement will entail?	• During the screening visit, participants will be assessed to see whether they would be suitable for the study.
	
	• During the study, participants will need to attend five study appointments with the study team at the Charing Cross Hospital (London, UK). Two follow-up telephone calls will also be planned between visits.
	
	• At every visits, participants will be asked to:
	  • complete different tests that will assess their memory and attention (with breaks in between)
	  • complete some tests to evaluate the possible treatment side-effects (i.e. sleepiness, blood pleasure).
	
	Further information on the procedures, tests and 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 45 years of age or older. • Have a diagnosis of probable Alzheimer's disease through clinical and neuropsychological examination (NINCDS/ADRDA criteria). • Take one of the three main standard recommended medications (Donepezil, Galantamine or Rivastigmine) at a stable dose for preceding 12 weeks. • Be willing to complete a memory test (MMSE). To be able to participate, the score of this test should suggest that the participant has a cognitive impairment that is very mild, mild or moderate (i.e. score between 10-30). • Be willing to have a study partner.

Who cannot participate in the study?	Exclusion criteria include:
	• Labile blood pressure (blood pressure fluctuates far more than usual) or new antihypertensive medication (drugs to treat high blood pressure) started within 3 weeks.
	• Treatment with other medications known to potentiate experimental drug's effects (e.g. antipsychotics).
	• A disease that may interfere with the safety, tolerability and/or study assessments, or put the participant at special risk (e.g. cardiac heart block, severe renal impairment or severe hepatic impairment).
	• A medical or neurological condition that could impact on the cognition or on the performance of the participant on cognitive assessments:
	  • Myocardial infarction (heart attack)
	  • History of unexplained syncope (loss of consciousness and muscle strength) within the last 12 months.
	• Treatment with other medications known to potentiate experimental drug's effects (e.g. antipsychotics).
	• Weight less than 45 kg.
	• Pregnancy.
	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	• United Kingdom
Estimated start date of recruitment	January 2019

6. Information for your doctor			
EudraCT Number:	2016-002598-36	**Clinicaltrials.gov identifier**	NCT03116126
Study contact information	020 3311 5228 Memory.research@imperial.nhs.uk		
Link to full text	https://clinicaltrials.gov/ct2/show/NCT03116126		

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on July 2019.
- ✓ This document has not 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.