Alzheimer Europe

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

CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

COGNITE STUDY

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COGNITE study

1. Study Information	
Name of the study	Safety and Efficacy Study of ALZT-OP1 in Subjects With Evidence of Early Alzheimer's Disease
Study sponsor	AZTherapies
Disease	Alzheimer's disease
Phase	Phase III

2. Information about the drug that will be tested in the study	
Name of drug	ALZT-OP1 (combination of ALZT-OP1a + ALZT-OP1b)
Administration	• ALZT-OP1a: a capsule for inhalation • ALZT-OP1b: a tablet for oral administration
Is the drug already on the market for another medical condition?	Yes • ALZT-OP1a: also known as cromolyn (widely used to treat asthma) • ALZT-OP1b: also known as ibuprofen (anti-inflammatory)
Will all participants receive the same drug?	Participants will be selected by chance to receive one of four possible treatments: • One capsule of ALZT-OP1a and one tablet of placebo • One capsule of placebo and one tablet of ALZT-OP1b • One capsule of ALZT-OP1a and one tablet of ALZT-OP1b • One capsule of placebo and one tablet of placebo (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 evaluate the safety and efficacy of treatment with an ALZT-OP1 combination (ALZT-OP1a + ALZT-OP1b) to slow down, arrest, or reverse deficiencies in

	cognition and functioning, in participants with evidence of early Alzheimer's disease.
How long will the treatment last?	• The study will last one and a half years (seven study visits).
What will your involvement entail?	• During the study, participants will be asked to complete a test that will assess their memory, orientation, judgment and problem solving, hobbies, personal care and community affairs (this is a test called CDR-SB). • Participants will be also requested to complete some other tests such as a physical examination, electrocardiography (recording the electrical activity of the heart) and laboratory tests in order to evaluate the emergent adverse events (unfavourable signs, symptoms or diseases temporally associated with the use of the drug tested in the study). Further information on the procedures 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 55 and 79 years old. • At least have 8 years of education. • Have a reliable study partner who has frequent contact with the participant. The study partner will need to accompany the participant to all study visits. • Have noticed changes in their memory. This change should be reported by the participant or by the study partner. • Have noticed changes in their everyday behaviour. • Be healthy and medically stable for 4 weeks prior to study start.

	• Have a Clinical Dementia Rating (CDR) Scale of 0.5 (the CDR is a scale used to evaluate the severity or stage of dementia. This scale ranges from 0 to 5, with 0 indicating no dementia and 5 severe dementia). • Have results of a lumbar puncture (CSF). This procedure will help to determine if there is abnormal levels of a protein called amyloid in the brain. Only participants who have results with evidence of early Alzheimer's disease will be able to participate in the study (i.e. CSF Aβ-42 levels of 180-690 pg/mL).
Who cannot participate in the study?	People cannot participate if they have: • Any other type of neurological disease that is not Alzheimer's disease. • Major depressive episode within the past 6 months. • History of schizophrenia (mental disorder which affects how a person thinks, feels and acts). • Alcohol or drug abuse or dependence within the past 3 years. • Currently taking cromolyn, or have taken cromolyn with the past 12 months. • Daily use of aspirin exceeding standard of care guidelines. • Allergy to cromolyn or ibuprofen or aspirin. • A pregnancy or breast-feeding for female participants. • Severe renal or liver disorders. 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 countries involved the trial	• Bulgaria • Czech Republic • Hungary • Poland
Estimated start date of recruitment	September 2015

6. Information for your doctor			
EudraCT Number:	2015-002147-34	**Clinicaltrials.gov identifier**	NCT02547818
Study contact information	david.brazier@aztherapies.com delmaleh@aztherapies.com		
Link to full text	https://clinicaltrials.gov/ct2/show/study/NCT02547818		

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on August 2019.
- ✓ The pharmaceutical company running this trial (AZTherapies) has reviewed this document.
- ✓ This document has been reviewed by a member of the European Working Group of People with Dementia.