Alzheimer Europe

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

CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

LUCIDITY STUDY

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LUCIDITY study

1. Study Information	
Name of the study	Safety and efficacy of TRx0237 in subjects with Alzheimer's disease followed by open-label treatment
Study sponsor	TauRx Therapeutics Ltd
Disease	People with mild or mild to moderate Alzheimer's disease
Phase	Phase 3

2. Information about the drug that will be tested in the study	
Name of drug	TRx0237 (hydromethylthionine)
Administration	2 tablets taken orally twice a day
Is the drug already on the market for another medical condition?	No
Will all participants receive the same drug?	Participants will be selected at random to either receive one of the following options: • 2 tablets of 4 mg of TRx0237 administered twice daily (16 mg/day) • A tablet of 4 mg of TRx0237 and a placebo tablet administered twice daily (8 mg/day) • 2 placebo tablets administered twice daily (also called a dummy treatment which is a 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 or the placebo.

3. Information about participating in the trial	
What are the researchers trying to find out?	• The purpose of this study is to determine the safety and efficacy of TRx0237 in the treatment of people with Alzheimer's disease compared to placebo
How long will the treatment last?	• 12 months plus a further 12 months open-label treatment where every participant takes the drug.

What your involvement will entail?	• Prior to the study, potential participants will be assessed for their eligibility to participate in the study. This will require 2-3 separate visits to the study centre and involve brain scans (PET, MRI) • During the study participants will be asked to undertake further MRI scans to review specific changes in brain volume. • Participants will be requested to attend the study centre at regular intervals for medical check-ups and cognitive assessments requiring the completion of oral and written tests. They should be accompanied on these visits by their study partner • Participants will be also requested to provide blood samples for laboratory tests to evaluate the side effects of the drug (this refers to the detection of any unfavourable signs, symptoms or conditions temporarily associated with the use of the drug tested in the study) 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: • Up to 90 years of age • Have a diagnosis of probable Alzheimer's disease • Have a score between 16-27 points in the MMSE test (a test about your memory) and 0.5 to 2 in the Clinical Dementia Rating-Global Score (CDR-GS) • Be fluent in the language used at the study site • Be willing to have at least a study partner who has a sufficient contact with the participant, is willing to accompany the

	participant to all study visits, provides the necessary information about the participant's memory, behaviour and functioning • Must not be taking an anti-dementia drug (e.g. acetylcholinesterase inhibitor, memantine) for at least 2 months prior to the screening visit • Females must be sterile (e.g. have undergone surgical operation, be post-menopausal, or use adequate contraception).
Who cannot participate in the study?	Exclusion criteria include: • Any other type of neurological disease that is not Alzheimer's disease (e.g. epilepsy) • History of schizophrenia (mental disorder which affects how a person thinks, feels and acts) or other depressive disorder • Treatment with other medications known to potentiate experimental drug's effects (e.g. antipsychotics) • Diagnosis of cancer within the past 2 years except if considered to not being linked with the disease for at least 2 years • Have any contraindication to brain MRI scans (due to having prostheses, implants, a pacemaker or claustrophobia) • Clinically significant cardiovascular or symptoms of respiratory failure • A pregnancy or breast-feeding for female participants • Resides in dependency facilities (i.e. hospital, care facility) 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 in the trial	• Belgium • Italy • France • Poland • Spain • United Kingdowm
Estimated start date of recruitment	March 2020

6. Information for your doctor	
Clinicaltrials.gov identifier	NCT03446001
Study contact information	Rebecca Andersen info@taurx.com
Link to full text	https://clinicaltrials.gov/ct2/show/NCT03446001

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov website) on September 2020.
- ✓ This document has 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.