Alzheimer Europe

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

CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

SYMBAD STUDY

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SYMBAD study

1. Study Information	
Scientific title	A Pragmatic, Multi Centre, Double-blind, Placebo Controlled Randomised Trial to Assess the Safety, Clinical and Cost Effectiveness of Mirtazapine in Patients With Alzheimer's Disease (AD) and Agitated Behaviours
Study sponsor	University of Sussex
Disease	Alzheimer's disease and agitated behaviours

2. Information about the drug that will be tested in the study	
Name of drugs	Mirtazapine
Administration	• A starting tablet taken orally once a day • increasing to 2 tablets per day after 2 weeks • and up to 3 tablets per day after 4 weeks.
Are the drugs already on the market for another medical condition?	Yes • Mirtazapine is an antidepressant.
Will all participants receive the same drug?	Participants will be selected at random to either receive initially: • One tablet of 15 mg of Mirtazapine • One placebo tablet (also called a dummy treatment which is an inactive substance identical in appearance to the drug being tested). This will then be increased as described above. Neither the participant nor his/her 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, clinical and cost effectiveness of Mirtazapine in people with dementia.

How long will the treatment last?	• Participants will receive the treatment for 12 weeks and will be followed up for one year (with tests at 6 months and 1 year).
What will your involvement entail?	• During the study, participants will be asked to complete a questionnaire that will assess their agitation (this is a test called CMAI) and other tests to measure clinical variables. 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 18 years of age or older • Be diagnosed with probable Alzheimer's disease • Be diagnosed with agitated behaviours • Complete a questionnaire that will assess their agitation (CMAI). To be able to participate, the score of this test should suggest that the participant has agitated behaviours (i.e. score of 45 or greater).
Who cannot participate in the study?	People cannot participate if they have: • A current treatment with antidepressants, anticonvulsants or antipsychotics • Contraindications to the administration of mirtazapine • History of reduced ability to produce blood cells (bone marrow depression) • History of hepatic disorder (hepatic porphyrias) • Women of childbearing potential. 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 2017

6. Information for your doctor			
EudraCT Number:	2015-003410-25	**Clinicaltrials.gov identifier**	NCT03031184
Study contact information	Sube Banerjee S.Banerjee@bsms.ac.uk 01273678472		
Link to full text	https://clinicaltrials.gov/ct2/show/NCT03031184		
Study website	https://www.uea.ac.uk/hta-symbad/home		

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