Alzheimer Europe

Making dementia a priority:
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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

DESPIAD STUDY

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DESPIAD study

1. Study Information	
Name of the study	Depletion of Serum Amyloid P Component In Alzheimer's Disease (DESPIAD). Double-blind placebo controlled randomised phase IIb trial of SAP depletion by CPHPC in mild Alzheimer's disease.
Study sponsor	University College London
Disease	Alzheimer's disease
Phase	Phase IIb

2. Information about the drug that will be tested in the study	
Name of drug	CPHPC (also called miridesap)
Administration	The drug will be administered via a subcutaneous injection (an injection under the skin) three times per day.
Is the drug already on the market for another medical condition?	No
Will all participants receive the same drug?	Participants will be selected by chance to receive one of the following options: • A subcutaneous injection of CPHPC • A subcutaneous injection of placebo (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 the study is to evaluate the safety, tolerability and potential effectiveness of 52 weeks exposure to CPHPC compared to placebo for the treatment of Alzheimer's disease.
How long will the treatment last?	• Participants will be treated for one year and the trial will run for about three years.

What your involvement will entail?	• During the study, participants will be asked to complete some laboratory tests to evaluate the side effects (it refers to unfavourable signs, symptoms or diseases temporally associated with the use of the drug tested in the study) • Participants will be asked to undertake brain scans (MRI, PET) and lumbar punctures (CSF) to see changes in amyloid and tau deposition in the brain • Participants will be asked to complete different tests that will assess their cognition (this is tests called PACC and NPI) • Complete a test that will assess their memory, orientation, judgment and problem solving, personal care and community affairs (this is a test called CDR) • Complete a memory test (MMSE). Further information on the 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, participants must: • Be 50 to 85 years old • Have a score between 20-28 points in the MMSE test (a test about your memory). This would suggest that the person has an impairment that is at a mild stage • Have results of brain scans consistent with the clinical diagnosis of Alzheimer's disease • Have a study partner who has a sufficient contact with the participant, is willing to accompany the participant to all study visits and if necessary assist the injections

	• Agree to undergo brain scans and lumbar puncture • Be willing to use effective contraception for the duration and of the trial (i.e. women of child bearing potential and males with a partner of child bearing potential).
Who cannot participate in the study?	Exclusion criteria include: • Ongoing neurological disorders, major psychiatric disorder or medical condition that may interfere with the safety or study assessments or could be the cause of the cognitive impairment • Severe renal or liver disorders • Treatment with anticoagulants (i.e. warfarin, rivaroxaban, apixaban or dabigatran). Low dose of aspirin or clopidogrel are permitted • If the person is taking an approved anti-dementia medication (i.e. donepezil, rivastigmine, galantamine or memantine) the dosing regimen must have been stable for at least 3 months prior to the screening visit • Have participated in a recent clinical study within the last three months with the use of other experimental drugs • A pregnancy or lactation for female participants. 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	• UK
Estimated start date of recruitment	October 2018

6. Information for your doctor	
EudraCT Number:	2016-003284-19
Study contact information	Mr Chinaza Ezirim +44 20 3549 5438 c.ezirim@ucl.ac.uk
Link to full text	https://www.clinicaltrialsregister.eu/ctr-search/trial/2016-003284-19/GB

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrialsregister.eu website) on June 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.