Alzheimer Europe

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CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

MAPT-CS1 STUDY

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MAPT-CS1 study

1. Study Information	
Name of the study	Safety, tolerability, pharmacokinetics, and pharmacodynamics of IONIS-MAPTRx in patients with mild Alzheimer's disease
Study sponsor	Ionis Pharmaceuticals
Disease	Mild Alzheimer's disease
Phase	Phase I/II

2. Information about the drug that was tested in the study	
Name of drug	IONIS MAPTRx
Administration	The drug was administered via an intrathecal injection (an injection into the spinal canal) every month during 3 months.
Is the drug already on the market for another medical condition?	No
Did all participants receive the same drug?	Participants were selected by chance to receive one of the following options: • An intrathecal injection of IONIS-MAPTRx, 4 different dose levels were tested • An intrathecal injection of placebo (a substance identical in appearance to the drug being tested with no active therapeutic effect). Neither the participant nor their doctor knoew 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, pharmacokinetics, and pharmacodynamics of IONIS-MAPTRx in people with mild Alzheimer's disease.
How long the treatment last?	• Around 10 months • 4 visits were planned for dosing and 5 visits in between doses and as follow-up (post-treatment).

What your involvement entailed?	During the study, participants were asked to: • Do laboratory tests to evaluate the emergent adverse events (unfavourable signs, symptoms, diseases temporally associated with the use of the drug tested in the study) • Do some blood tests • Undergo regular brain scans (MRI) and CSF examination (spinal tap) during the course of the study. 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 between 50 and 74 years old, inclusive • Have a diagnosis of mild Alzheimer's disease including evidence of abnormal accumulation of amyloid or Tau protein in their brain (CSF examination) • Have a body mass index between 18 and 35 kg/m^2 and total body weight > 50 kg • Have a study partner who has a sufficient contact with the participant, is willing to accompany the participant to all study visits and to be available by phone if needed.
Who cannot participate in the study?	Exclusion criteria include: • A medical condition that may interfere with the safety, tolerability and/or study assessments, or put the participant at special risk • Utilisation of certain brain or antipsychotic drugs within the past month.

	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 was the study be conducted?	
European countries involved in the trial	• Finland • Germany • Netherlands • Sweden • UK
Estimated start date of recruitment	June 2017

6. Information for your doctor			
EudraCT Number:	2016-002713-22	**Clinicaltrials.gov identifier**	NCT03186989
Study contact information	patients@ionisph.com		
Link to full text	https://clinicaltrials.gov/ct2/show/NCT03186989		

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