

CLINICAL TRIALS WATCH

ACCESSIBLE EASY READ INFORMATION ON:

TRONTIER 1 STUDY

TRONTIER 1 study

| 1. Study Information | |
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| Name of the study | A clinical trial of trontinemab in participants with early symptomatic Alzheimer's disease |
| Study sponsor | F. Hoffmann- La Roche |
| Disease | Early Alzheimer's disease (mild cognitive impairment to mild dementia due to Alzheimer's disease) |
| Phase | Phase III |

| 2. Information about the drug that will be tested in the study | |
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| Name of drug | Trontinemab |
| Administration | The drug will be administered via an intravenous infusion (an injection into the vein) |
| Is the drug already on the market for another medical condition? | No |
| Will all participants receive the same drug? | <p>Participants will be selected by chance to receive one of the following options:</p> <ul style="list-style-type: none">• An intravenous infusion of trontinemab• An intravenous infusion of placebo (also called a dummy treatment which is an inactive substance being tested with no active therapeutic effect). <p>Neither the participant nor their doctor will know if the person is receiving the investigational drug or the placebo.</p> |

| 3. Information about participating in the trial | |
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| What are the researchers trying to find out? | <ul style="list-style-type: none">• The purpose of the study is to assess the efficacy and safety of trontinemab in people with early symptomatic Alzheimer's disease (mild cognitive impairment to mild dementia due to Alzheimer's disease) |
| How long will the treatment last? | <ul style="list-style-type: none">• 72 weeks |

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| <p>What your involvement will entail?</p> | <ul style="list-style-type: none"> • During the study, participants will be asked to complete tests that will assess their memory, cognition, functional and daily activities (MMSE, CDR-SB, ADAS-Cog-13, ADCS-ADL, iADRS, CDR-GS) • Complete some laboratory tests and neurological examination to evaluate the emergent adverse events (unfavourable signs, symptoms or diseases temporally associated with the use of the drug tested in the study) • Undergo brain scans (PET) or if this is not possible undergo a CSF examination (lumbar puncture). <p>Further information on the procedures, tests and number of visits can be obtained from the study team.</p> |
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| <p>4. Who can participate in this study?</p> | |
| <p>Who can participate in the study?</p> | <p>To take part in the study, participants must:</p> <ul style="list-style-type: none"> • Be between 50 and 90 years old • Have adequate visual and auditory acuity (eyewear and hearing aids are permitted) • Have evidence of abnormal accumulation of amyloid in the brain (determined through amyloid PET scan) • Have a diagnosis of probable Alzheimer’s disease dementia or mild cognitive impairment • Have a score ≥ 22 in the MMSE test and of 0.5 or 1.0 in the CDR-GS test. This would suggest that the person has mild cognitive impairment • Have a study partner is willing to support and participate in the research. |

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| <p>Who cannot participate in the study?</p> | <p>Exclusion criteria include:</p> <ul style="list-style-type: none"> • A neurological disease other than Alzheimer’s disease that may affect cognition • Have a current serious medical condition or abnormality that could increase the risk to their safety or could interfere with the results of this study (e.g. cerebrovascular disease, significant intracranial mass) • A disease that may interfere with the safety or study assessments (e.g., cardiovascular, hepatic, renal disease). <p>The above list is not exhaustive. It includes the most common conditions and diseases that might exclude people from the study.</p> |
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| <p>5. Where and when will the study be conducted?</p> | |
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| <p>European countries involved in the trial (active)</p> | <ul style="list-style-type: none"> • France • Germany • Italy • Poland • Spain • UK |
| <p>European countries involved in the trial (planned)</p> | <ul style="list-style-type: none"> • Denmark |
| <p>Estimated start date of recruitment</p> | <p>November 2025</p> |

| 6. Information for your doctor | | | |
|---------------------------------------|---|---------------------|-------------------|
| Clinicaltrials.gov identifier | NCT07169578 | EU CT Number | 2024-518006-40-00 |
| Study contact information | global-roche-genentech-trials@gene.com | | |
| Link to full text | https://clinicaltrials.gov/study/NCT07169578 https://euclinicaltrials.eu/ctis-public/view/2024-518006-40-00 | | |
| Study's website | https://forpatients.roche.com/en/trials/neurodegenerative-disorder/ad/a-study-of-trontinemab-in-participants-with-early-sympt-02194.html | | |

- ✓ The information contained in this document is based on information available on public registries (e.g. clinicaltrials.gov, CTIS websites) in January 2026.
- ✓ The pharmaceutical company running this trial has reviewed this document.
- ✓ This document has been reviewed by a member of the European Dementia Carers Working Group.