ForPatients
by Roche

Alzheimer's Disease (AD)

A clinical trial to look at how well RO7269162 works in people who are at risk of Alzheimer’s disease or who have mild cognitive impairment due to Alzheimer’s disease and how safe RO7269162 is at different doses

A Study to Evaluate the Safety and Biomarker Effects of RO7269162 in Participants at Risk for or at the Prodromal Stage of Alzheimer's Disease (AD)

Trial Status	Trial Runs In	Trial Identifier
Recruiting	9 Countries	NCT06402838 2023-506183-13-00 BP44745

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This clinical trial is recruiting people who either are at risk of AD - have build-up of beta-amyloid, but have no clinical symptoms, or with a diagnosis of mild cognitive impairment. People can take part if they have a certain level of plaques (beta-amyloid) in the brain, shown by a positron emission tomography (PET) scan, a medical imaging technique in which tracers are injected to visualize specific pathological processes in the brain. People who take part in this clinical trial (participants) will be given RO7269162 OR placebo for up to about 1 and a half years. The clinical trial team will see them every 3 weeks in the first 3 months and then every 6 weeks until the end of the trial. These hospital visits will include checks to see how the participant responds to the treatment and any side effects they may have. The total time of participation in the clinical trial will be 90 weeks.

Hoffmann-La Roche	Phase 2
Sponsor	Phase

NCT06402838 2023-506183-13-00 BP44745
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=60 Years & <= 85 Years	No

1. Why is the GABRIELLA clinical trial needed?

Alzheimer's disease (AD) is a medical condition caused by changes in the brain. It can affect memory, behaviour, problem-solving skills and daily activities. AD is caused by changes in the brain, which can occur up to 20 years before the first symptoms develop. It is thought to be caused by changes in two proteins: beta-amyloid and tau. Plaques (build-up of beta-amyloid) and tangles (twisted threads of tau) are the main reasons that nerve cells are damaged. These two proteins are currently the main focus for many researchers aiming to find treatments that could potentially slow or stop AD. The damage to nerve cells in the brain gets worse over time in people with AD, affecting a person's ability to live independently. Prodromal Alzheimer's, also known as 'mild cognitive impairment' (MCI) due to Alzheimer's disease, is a stage when a person starts to have trouble with their memory or other thinking abilities but can still do most things they did before, like work. People in this stage are more likely to develop 'dementia', the most severe stage of AD.

Current treatments aim to relieve the symptoms of AD, but there is currently no cure. In some countries, medicines called 'antibodies' are approved for AD – these lower the amount of beta-amyloid by helping the body's immune system to remove it. This slows disease progression that can otherwise lead to memory loss and difficulty with thinking.

RO7269162 is a drug that changes how beta-amyloid proteins are made, which could mean fewer plaques in the brain and slow down AD. RO7269162 is an experimental drug, which means that it has not been approved by health authorities to treat AD.

This clinical trial aims to compare the effects, good or bad, of RO7269162 against a substance with no active ingredients (also known as a 'placebo') in people with AD.

2. How does the GABRIELLA clinical trial work?

This clinical trial is recruiting people who either are at risk of AD – have build-up of beta-amyloid, but have no clinical symptoms, or with a diagnosis of prodromal AD. People can take part if they have a certain level of plaques (beta-amyloid) in the brain, shown by a positron emission tomography (PET) scan, a medical imaging technique used to visualise activity in the brain. People who take part in this clinical trial (participants) will be given RO7269162 OR placebo for up to about 1 and a half years. The clinical trial team will see them every 3 weeks in the first 3 months and then every 6 weeks until the end of the trial. These hospital visits will include checks to see how the participant responds to the treatment and any side effects they may have. The total time of participation in the clinical trial will be 1 and a half years. Participants can stop trial treatment and leave the clinical trial at any time.

3. What are the main endpoints of the GABRIELLA clinical trial?

The main clinical trial endpoints (the main results measured in the trial to see how safe the drug is and if it has worked) are the number and seriousness of any side effects and

changes in the amount of amyloid measured by PET scan after about 1 and a half years of treatment.

The other clinical trial endpoints include:

- Changes in the levels of markers in the blood and spinal fluid after 1 and a half years of treatment
- Levels of RO7269162 and its parts (once it is broken down by the body) in the blood and spinal fluid

4. Who can take part in this clinical trial?

People can take part in this trial if they are either at risk of AD but have no clinical symptoms, or with a diagnosis of MCI due to AD (e.g. prodromal AD), are between 60–85 years of age and have a body mass index (BMI) between 18–35kg/m2. People will also need a study partner who agrees to, and can provide information about the participant's ability to think, communicate and perform daily activities. People may not be able to take part in this trial if they have had a stroke that caused symptoms, or brain damage or cancer. People may also not be able to take part if they have certain other medical conditions such as heart, lung, liver or autoimmune problems, certain uncontrolled infections (e.g. COVID-19) or diabetes, or if they are pregnant or breastfeeding. People who have previously been given RO7269162 or other experimental drugs within 1 year or who cannot have the required trial procedures (such as scans), will not be able to join the trial.

5. What treatment will participants be given in this clinical trial?

Everyone in this clinical trial will join one of two groups randomly (like flipping a coin) and be given either:

- RO7269162 OR placebo, given as a pill/s (to be swallowed) every day for up to 1 and a half years

Participants will have a 75% chance of being placed in the RO7269162 group. This is a 'placebo-controlled' clinical trial, which means that one of the groups will be given a placebo – it looks like the drug being tested but does not contain any real medicine. Comparing results from the different groups helps the researchers know whether any changes seen result from the drug or occur by chance.

This is a double-blinded trial, which means that neither the participant nor the clinical trial doctor can choose or know the group the participant is in, until the trial is over. This helps to prevent bias and expectations about what will happen. However, the participant's clinical trial doctor can find out which group the participant is in, if their safety is at risk.

6. Are there any risks or benefits in taking part in this clinical trial?

The safety or effectiveness of the experimental treatment or use may not be fully known at the time of the trial. Most trials involve some risks to the participant. However, it may not be greater than the risks related to routine medical care or the natural progression of the health condition. People who would like to participate will be told about any risks and benefits of taking part in the clinical trial, as well as any additional procedures, tests, or assessments they will be asked to undergo. All of these will be described in an informed consent document (a document that provides people with the information they need to decide to volunteer for the clinical trial).

Risks associated with the clinical trial drug

Participants may have side effects (an unwanted effect of a drug or medical treatment) from the drug used in this clinical trial. Side effects can be mild to severe, even life-threatening, and vary from person to person. Participants will be closely monitored during the clinical trial; safety assessments will be performed regularly.

Participants will be told about the known side effects of RO7269162 and possible side effects based on human and laboratory studies or knowledge of similar drugs. Participants will be told about any known side effects of swallowing pills.

Potential benefits associated with the clinical trial

Participants' health may or may not improve from participation in the clinical trial. Still, the information collected may help other people with similar medical conditions in the future.