ForPatients
by Roche

Acute Ischemic Stroke

A Phase I, open-label, multi-center, pharmacokinetic, pharmacodynamic and safety study of tenecteplase in adult patients with acute ischemic stroke

Trial Status	Trial Runs In	Trial Identifier
Recruiting	1 Countries	GC43996

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

Trial Summary:

A study to evaluate the safety, processing by the body and response of the body to tenecteplase in adults with acute ischemic stroke

F. Hoffmann-La Roche Sponsor	**Phase 1** Phase

GC43996
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Both	Adult	No

Background and study aims

Acute ischemic stroke (AIS) occurs when the blood supply to certain parts of the brain is cut off or reduced due to the formation of a clot in a blood vessel of the brain. This causes a lack of oxygen (ischemia) and nutrients in the brain cells eventually leading to brain cell degradation. The human body produces a protein called tissue plasminogen activator (t-PA) which helps in breaking down these clots (thrombolysis). Treatments with t-PA help in restoring the blood flow and prevent tissue damage to brain cells. Tenecteplase is a modified form of human t-PA that helps to restore the blood flow, thereby improving health outcomes in participants suffering from AIS. The aim of this study is to determine the way the body absorbs (takes in) and breaks down the drug tenecteplase. This study also looks to see how proteins in blood change after tenecteplase is administered. The study also collects information to determine how safe it is to give tenecteplase to people having

an acute ischemic stroke. Tenecteplase is an experimental drug, which means health authorities have not approved tenecteplase for the treatment of AIS.

Who can participate?

Patients aged 18 years and above with a confirmed diagnosis of AIS

What does the study involve?

Participants will need to be a part of this study for about 30 days. This study will have three parts:

1. A screening visit, where certain tests would be done along with the evaluation of the participant's medical history and ongoing medications to determine if the participant is eligible to take part in the study.

2. The treatment period: eligible participants will be enrolled, and a small amount of blood will be withdrawn after which participants will be given a single dose of the study drug intravenously (through a needle in the arm that is attached to a tube that is connected to a bag full of saline). Participants will be visited by the study team after 20 minutes and then after 2, 6, and 24 hours of drug administration to collect blood samples for analysis.

3. A follow-up period during which participants will have check-up visits with the study team on the day of their discharge from the hospital or Day 5, whichever is earlier, and 30 days after the study drug administration. The participant will have to visit the clinic or will be contacted telephonically for the follow-up procedures.

What are the possible benefits and risks of participating?

Participants will not receive any direct medical benefit. The health of participants may or may not improve, but the information gained from this study may help other people who have a similar medical condition in the future.

Participants may have side effects from the drug (tenecteplase) or procedures used in this study. These can be mild to severe, and they can vary from person to person. The potential side effects associated with tenecteplase and other procedures are listed below:

Risks associated with tenecteplase:

Very common side effects include bleeding that a participant might experience due to the drug or the procedure of drug administration.

Common side effects include blocking of blood vessels by blood clots (thromboembolism), blocking of arteries due to cholesterol buildup (cholesterol embolism) and an irregular heartbeat (arrhythmia).

Less common side effects include an allergic reaction (hypersensitivity), inability of the heart to pump enough blood (cardiogenic shock), heart blockage (atrioventricular block), fluid in the lungs (pulmonary oedema), heart failure, heart stopping (cardiac arrest), reduced blood flow to the heart (recurrent myocardial ischemia), a complication after a heart attack (myocardial reinfarction), tear in the heart (myocardial rupture), constriction of the heart by fluid buildup around the heart (cardiac tamponade), swelling of the tissue around the heart (pericarditis), fluid buildup in the pericardial cavity around the heart (pericardial effusion), backflow of blood in the heart due to the heart's mitral valve failing to close (mitral regurgitation), electrical activity in the heart but no pulse (electromechanical dissociation), Nausea and/or vomiting, and low blood pressure (hypotension)

Risks associated with the study procedures:

Magnetic resonance imaging (MRI) scanning: During MRI scanning, participants might experience anxiety or fear of being in small places (claustrophobia). The contrast agent used while performing an MRI scan might cause pain, bruising, or infection at the injection site, nausea, headache, hives, temporary low blood pressure, chest pain, back pain, fever, weakness, and seizures.

Computed tomographic (CT) scan: The long term harmful effects of radiation exposure from multiple X-rays over a period of time is unknown. The contrast agent used during CT scans may cause a decrease in kidney function (acute kidney injury)

There may be a risk in exposing an unborn child to the study drug, and all risks are not known at this time. Women and men must take precautions to avoid exposing an unborn child to the study drug. Participants who are pregnant, become pregnant or are currently breastfeeding cannot take part in this study.