ARTEMIS - A Research Study to Look at How Ziltivekimab Works Compared to Placebo in People With a Heart Attack

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Key inclusion: * Age 18 years or above at the time of signing the informed consent. * Hospitalisation for acute myocardial infarction with evidence of type 1 myocardial infarction (MI) by invasive angiography performed at site with percutaneous coronary intervention (PCI) capabilities. * ST-segment elevation myocardial infarction (STEMI) with all the following: a) Relevant onset of symptoms suggestive of cardiac ischaemia within 12 hours before hospitalisation, at the investigator's discretion. b) Electrocardiogram (ECG)-changes (in the absence of left ventricular hypertrophy or left bundle branch block): ST-segment elevation at the J point in at least two contiguous leads greater than or equal 0.25 (millivolt) mV in men less than 40 years, greater than or equal 0.2 mV in men greater than or equal 40 years, or greater than or equal 0.15 mV in women in leads V2-V3; and/or greater than or equal 0.1 mV in all other leads. OR * Non-ST-segment myocardial infarction with all the following: a) Relevant onset of symptoms suggestive of cardiac ischaemia within 24 hours before hospitalisation, at the investigator's discretion. b) Rise and/or fall in car-diac troponin I or T with at least one value above the 99th percentile upper reference limit. * Possibility for both randomisation and administration of the loading dose of study intervention as early as possible after invasive procedure, and latest within 36 hours of hospitalisation (time 0) for STEMI, and latest within 72 hours of hospitalisation (time 0) for NSTEMI. * Presence of at least one of the following criteria confirmed based on the participant's medical records and/or medical history interview: a) Any prior MI. b) Prior coronary revascularisation. c) Diabetes mellitus treated with ongoing glucose-lowering agent(s). d)Known chronic kidney disease (CKD) (estimated glomerular filtration rate (eGFR) greater than or equal to 15 and less than 60 milliliter per minute per 1.73 square meter (mL/min/1.73 m\^2). e) Prior ischaemic stroke. f) Known carotid disease or peripheral artery disease in the lower extremities. g) Multivessel coronary artery disease (current/prior). h) For STEMI patients only: anterior MI at index acute myocardial infarction (AMI) Key exclusion: * Use of fibrinolytic therapy for treatment of the current AMI. * Chronic heart failure classified as being in New York Heart Association (NYHA) Class IV. * Ongoing haemodynamic instability defined as any of the following: a) Killip Class III or IV. b) Sustained and/or symptomatic hypotension (systolic blood pressure less than 90 millimeters of mercury (mmHg)). * Severe kidney impairment defined as any of the following: a) eGFR less than 15 mililitre per minute per 1.73 m\^2. b) Chronic haemodialysis or peritoneal dialysis. * Known alanine aminotransferase (ALT) greater than 8 x upper limit of normal (reference range) (ULN). * Severe hepatic disease defined as at least one of the following: a) Previously known or current hepatic encephalopathy (clinical evaluation). b) Previously known or current ascites (clinical eval-uation). c) Jaundice (clinical evaluation). d) Previous oesophageal/gastric variceal bleeding. c) Known hepatic cirrhosis. * Major cardiac surgical (including but not restricted to coronary artery bypass graft surgery (CABG)), non-cardiac surgical, or major endoscopic procedure (thoracoscopic or laparoscopic) within the past 60 days or any major surgical procedure planned at the time of randomisation or as treatment for the current AMI (CABG). Deferred (staged)percutaneous coronary intervention for a non-culprit vessel identified during the current AMI is allowed. * Clinical evidence of, or suspicion of, active infection at the discretion of the investigator. * Known (acute or chronic) hepatitis B or hepatitis C. * History or evidence of untreated latent tuberculosis (TB) such as (but not limited to): a) History of a positive TB test or chest X-ray compatible with latent TB; and TB treatment initiated less than 28 days prior to randomisation. b) Participants with TB risk factors but unwilling to undergo TB treatment if confirmed positive for latent TB based on central laboratory test at baseline (visit 2).

Conditions & Interventions

Interventions:

DRUG: Ziltivekimab, DRUG: Placebo

Conditions:

Cardiovascular Risk, Acute Myocardial Infarction (AMI)

More Information

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Principal Investigator:

Phase: PHASE3

IRB

Number:

System ID: NCT06118281