A Study of TAK-330 to Reverse the Effects of Factor Xa Inhibitors For Adults Needing Urgent Surgery

NCT05156983

Status	RECRUITING
Phase	Phase 3
Sponsor	Takeda
Enrollment	328 participants

Key Eligibility Criteria

Inclusion (5)

- Participant or legally authorized representative willing to sign e-consent/written informed consent form.
- Participants at least 18 years of age at enrollment.
- Participant currently on treatment with oral Factor Xa inhibitor (rivaroxaban, apixaban, edoxaban).
- In the opinion of the surgeon, the participant requires an urgent surgery/procedure that is associated with high-risk of intraoperative bleeding within 15 hours from the last dose of Factor Xa inhibitor and requires a reversal agent for suspected direct oral Factor Xa inhibitor-related coagulopathy. For participants who are beyond the 15-hour window, eligibility requires proof of elevated plasma anti-Factor Xa (FXa) levels using either specific direct oral anti-coagulant (DOAC)-calibrated (apixaban, rivaroxaban or edoxaban) anti-FXa levels of greater than (\>) 75 nanograms per milliliter (ng/mL), or heparin calibrated anti-FXa assay levels of \>0.5 international unit per milliliter (IU/mL) at screening.
- Women of childbearing potential should have a negative pregnancy test documented prior to enrollment.

Exclusion (19)

- The participant has an expected survival of less than 30 days, even with best available medical and surgical care.
- Recent history (within 90 days prior to screening) of venous thromboembolism, myocardial infarction (MI), disseminated intravascular coagulation (DIC), ischemic stroke, transient ischemic attack, hospitalization for unstable angina pectoris or severe or critical coronavirus 2 (SARS-CoV-2) infection.
- Active major bleeding defined as bleeding that requires surgery or transfusion of \>2 units of packed red blood cell (PRBC) or intracranial hemorrhage with the exception of subacute and chronic subdural hemorrhages with a Glasgow Coma Score (GCS) greater than or equal to (\>=) 9.
- Polytrauma for which reversal of Factor Xa-inhibition alone would not be sufficient to achieve hemostasis.
- Known prothrombotic disorder including primary antiphospholipid syndrome, antithrombin-3 deficiency, homozygous protein C deficiency, homozygous protein S deficiency, and homozygous factor V Leiden.

... and 14 more (see full listing online)

Locations (64 total)

University of Arkansas Medical Sciences, Arkansas City, Arkansas, United States
University of California Davis Health System, Sacramento, California, United States
Denver Metro Orthopedics, P.C., Englewood, Colorado, United States
... and 61 more locations