ForPatients
by Roche

Acute Kidney Injury

A Study to Evaluate the Efficacy and Safety of GDC-8264 in Preventing Cardiac Surgery-Associated Acute Kidney Injury (AKI) and Major Adverse Kidney Events (MAKE)

Trial Status	Trial Runs In	Trial Identifier
Recruiting	11 Countries	NCT06602453 2024-513125-23-00 GC45428

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase II, Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy and Safety of GDC-8264 in Preventing Cardiac Surgery-Associated Acute Kidney Injury and Major Adverse Kidney Events

Trial Summary:

The aim of this study is to evaluate the efficacy and safety of GDC-8264 compared with placebo in participants undergoing cardiac surgery who are determined to be at moderate to high risk of developing AKI and subsequent MAKE at 90 days after surgery (MAKE90). The study will be performed in two parts- Part 1 and Part 2.

Genentech, Inc.
Sponsor

Phase 2
Phase

NCT06602453 2024-513125-23-00 GC45428
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#40 Years	No

Inclusion Criteria:

- One of the following non-emergent cardiac surgery types that requires cardiopulmonary bypass (CPB) to be done in one procedure rather than separate procedures: Isolated Coronary Artery Bypass Grafting (CABG); Isolated Surgical Aortic Valve Replacement (AVR), Mitral Valve Replacement (MVR), Mitral Valve repair (MVr); Combined CABG+AVR, CABG+MVR, CABG+MVr, AVR+MVR, AVR+MVr

- At least one or at least two of the following AKI risk factors, depending on the type of surgery: age > 70 years, history of CKD with eGFR < 60 milliliters/ minutes/ 1.73 meter square (ml/min/1.73 m^2) within the last 6 months, diabetes (type 1 or type 2) requiring at least one oral hypoglycemic agent or insulin, history of chronic obstructive pulmonary disease (COPD) requiring medical therapy, left ventricular ejection fraction (LVEF) < 40%, preoperative anemia [hemoglobin <10 grams/deciliters (g/dL)]
- Stable kidney function with no known episodes of AKI within 2 weeks of screening

Exclusion Criteria:

- Need for renal replacement therapy (peritoneal dialysis or hemodialysis)
- Need for intra-aortic balloon pump, temporary mechanical circulatory support, or extracorporeal membrane oxygenation prior to scheduled surgery
- Presence of a durable left ventricular assist device
- Need for concurrent aortic surgery that requires circulatory arrest and deep hypothermia or repair of congenital heart defects
- Heart transplant
- Transcatheter valve replacements
- Hypotension or shock requiring hospital admission
- Cardiopulmonary resuscitation
- eGFR < 20 mL/min/1.73 m^2
- Heart failure with ejection fraction < 20%, or episode of decompensated heart failure requiring intervention within 2 weeks prior to screening
- History of kidney transplant or only one kidney (due to donation)
- Renal agenesis, total nephrectomy, or partial nephrectomy of > 50%