

# Potassium-Competitive Acid Blocker Versus pROton-Pump Inhibitor for GastroproTECTion Strategies In Patients at High Gastro-Intestinal Bleeding Risk Receiving Antithrombotic Therapy

NCT04416581

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Status	RECRUITING
Phase	Phase 4
Sponsor	Duk-Woo Park, MD
Enrollment	3,320 participants

## Key Eligibility Criteria

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### Inclusion (29)

- Patients 19 years of age or older with known cardiac and vascular disease who are receiving chronic use of antithrombotic drugs (either antiplatelets, oral anticoagulant (OAC), and its combinations). Specific clinical conditions that may confer a need for long-term antithrombotic therapy may include documented coronary artery disease (stable or unstable angina, acute coronary syndrome, a history of myocardial infarction, or any coronary revascularization), documented cerebrovascular disease (stroke or transient ischemic attack), known peripheral arterial disease or a history of peripheral arterial revascularization, atrial fibrillation, or valvular heart disease requiring interventions (transcatheter aortic valve replacement or transcatheter mitral-valve repair). Concomitant use of a proton pump inhibitor is strongly recommended in patients receiving aspirin monotherapy, DAPT (dual antiplatelet therapy; aspirin plus any P2Y12 inhibitors), DAT (dual antithrombotic therapy; antiplatelet drug plus OAC), TAT (triple antithrombotic therapy; DAPT plus OAC), or OAC monotherapy (warfarin or direct oral anticoagulants) who are at high risk of GI bleeding in order to reduce the risk of gastric bleed or GI events. Based on clinical guidelines, the use of P2Y12 inhibitor monotherapy (i.e. clopidogrel, ticagrelor, or prasugrel) is not considered in trial enrollment.
- On the basis of clinical guidelines and expert consensus documents, we defined a study population with an increased risk of gastrointestinal bleeding if they had a least 1 or more criteria of the following characteristics. Eligible patients for randomization must meet at least 1 characteristic of these criteria:
  - \\*Definition of patients who are at high risk of gastrointestinal bleeding
  - Age e65 years
  - Concomitant use of OAC and any antiplatelet therapy (mono or DAPT) (i.e., DAT or TAT)

... and 24 more (see full listing online)

### Exclusion (3)

- Active bleeding at the time of inclusion or a history of hereditary or acquired hemostatic disorder
- Any clinical contraindication to using of antithrombotic therapies (antiplatelet agents or OAC)
- Concurrent use of PPI or P-CAB within 4 weeks before randomization

## Locations (43 total)

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Hallym University Sacred Heart Hospital, Anyang, South Korea  
Bucheon Sejong Hospital, Bucheon-si, South Korea  
Kosin University Gospel Hospital, Busan, South Korea  
... and 40 more locations

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<https://clinicaltrials.gov/study/NCT04416581>

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