

Efficacy and Safety of Keverprazan-amoxicillin Dual Therapy for Helicobacter Pylori First-line Treatment

NCT07122024

Status	RECRUITING
Phase	Phase 4
Sponsor	Second Affiliated Hospital, School of Medicine, Zhejiang University
Enrollment	414 participants

Key Eligibility Criteria

Inclusion (5)

- Adult patients aged 18 to 65 years old, regardless of gender;
- H. pylori positive, diagnosed a 13C-urea breath test (13C-UBT), 1tC-urea breath test (1tC-UBT), H&E staining or bacterial culture;
- No previous history of H. pylori eradication therapy;
- Subjects able to independently complete the recording of the subject diary card;
- Subjects who fully understand the trial content, voluntarily participate in the trial, can complete the trial process, and sign the informed consent form.

Exclusion (9)

- Use of acid-suppressing drugs such as proton pump inhibitors (PPIs), potassium-competitive acid blocker (P-CAB), H2 receptor antagonists, etc., within 2 weeks before enrollment, or use of antibiotics within 4 weeks before enrollment;
 - Active peptic ulcer with complications such as bleeding, perforation, obstruction, canceration, etc.;
 - Previous history of esophageal or gastric surgery;
 - Severe systemic diseases, including diseases of major organs dysfunction such as (cardiac, pulmonary, cerebral), hepatic or renal impairment, malignant neoplasms, or other diseases;
 - Participants with allergies or hypersensitivity to keverprazan, rabeprazole, amoxicillin, clarithromycin, bismuth agents, including its excipients (such as mannitol, microcrystalline cellulose, crospovidone, hypromellose, magnesium stearate, etc.);
- ... and 4 more (see full listing online)

Locations (1 total)

The Second Affiliated Hospital Zhejiang University School of Medicine, Hangzhou, Zhejiang, China

<https://clinicaltrials.gov/study/NCT07122024>

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