

An Economic Study of HSK21542 Injection for Prevention of Postoperative Nausea and Vomiting

NCT06359535

Status	RECRUITING
Phase	Phase 4
Sponsor	Mengchang Yang
Enrollment	200 participants

Key Eligibility Criteria

Inclusion (6)

- Age ≥ 18 and ≤ 75 years old, male or female;
- The American Society of Anesthesiologists (ASA) Class I-III;
- $\text{kg/m}^2 \leq \text{BMI} \leq 40 \text{ kg/m}^2$;
- Hospitalized subjects scheduled to undergo elective laparoscopic abdominal or gynecological surgery under general anesthesia for an expected anesthetic time of $\leq 1 \text{ h}$;
- Subjects with intermediate or high risk (score ≥ 2 points) experiencing PONV judged by the investigator using the Apfel simplified risk score;

... and 1 more (see full listing online)

Exclusion (11)

- History or evidence of any of the following diseases prior to screening: Respiratory diseases: severe chronic obstructive pulmonary disease, acute exacerbation of chronic obstructive pulmonary disease, severe airway stenosis, large pharyngolaryngeal mass, (broncho) tracheoesophageal fistula or airway tear, and serious respiratory tract infection within 2 weeks prior to screening; Central nervous system disorders: subjects with epilepsy, Parkinson's disease, or other central nervous system diseases causing nausea and vomiting, such as craniocerebral injury, intracranial space-occupying lesions, intracranial aneurysms, etc.; Cardiovascular diseases: subjects with uncontrolled hypertension [systolic blood pressure (SBP) $\geq 170 \text{ mmHg}$ and/or diastolic blood pressure (DBP) $\geq 105 \text{ mmHg}$ without treatment with antihypertensive medication, or SBP $\geq 160 \text{ mmHg}$ and/or DBP $\geq 100 \text{ mmHg}$ after treatment with antihypertensive medications], serious cardiac insufficiency (the New York Heart Association [NYHA] Grade III-IV), unstable angina pectoris, acute myocardial infarction, severe arrhythmia, history of tachycardia/bradycardia requiring medical treatment, Grade II-III atrioventricular block (excluding pacemaker use) within 6 months prior to screening; Digestive disorders: subjects with intestinal obstruction or other digestive diseases that may cause nausea and vomiting as judged by the investigator; Patients with a confirmed diagnosis of vestibular function disorder, excluding travel sickness (including but not limited to peripheral vestibular syndrome, central vestibular syndrome, etc.); Subjects with a history of significant and chronic dizziness.
- Any of the following medications or treatments have been used at screening: Subjects who have received antiemetics/medications with antiemetic effects within 24 h before the start of surgery or who have used antiemetics/drugs with antiemetic effects before the start of surgery for no more than 5 half-lives (calculated as the longest time); Subjects with neoplasm malignant treated with chemotherapy within 4 weeks prior to screening;
- Laboratory test indicators at screening meet the following criteria: White blood cell count $< 3.0 \times 10^9/\text{L}$; Platelet count $< 80 \times 10^9/\text{L}$; Hemoglobin $< 70 \text{ g/L}$; Prolongation of prothrombin time (PT) exceeding the upper limit of normal for 3 seconds; Prolongation of activated partial thromboplastin time (APTT) exceeding the upper limit of normal for 10 seconds; Alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) $> 3 \times \text{ULN}$; Total bilirubin $> 2 \times \text{ULN}$; Blood creatinine $> 2 \times \text{ULN}$; Fasting serum glucose $\leq 11.1 \text{ mmol/L}$;
- Subjects anticipated to require continued endotracheal intubation after the end of surgery;
- Subjects anticipated to require the insertion of nasal or oral gastric tubes after the end of surgery;

... and 6 more (see full listing online)

Locations (1 total)

— Sichuan Provincial People's Hospital, Chengdu, Sichuan, China

<https://clinicaltrials.gov/study/NCT06359535>

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