Clinical Study on the Effectiveness and Safety of Succinylated Gelatin Electrolyte Sodium Acetate Injection

NCT06977750

Status	RECRUITING
Phase	Not Applicable
Sponsor	Nanjing Chia-tai Tianqing Pharmaceutical
Enrollment	104 participants

Key Eligibility Criteria

Inclusion (7)

- Age range is 18 to 65 years old (including boundary values), with no gender restrictions.
- Weight not less than 50 kg, weight not more than 100 kg, body mass index \[BMI=weight (kg)/height 2 (m2)\] within the range of 19.0\~30.0 kg/m2 (including critical values).
- Planned elective surgery with an estimated duration of less than 6 hours.
- The expected ANH blood collection volume is 10% to 15% of the total blood volume.
- Prior to enrollment, the Hb level of the subjects was e 110 g/L.

... and 2 more (see full listing online)

Exclusion (24)

- Individuals with a history of severe cerebrovascular disease or severe mental illness, who have been deemed unsuitable by the researchers to participate in this trial.
- Previous indications include heart valve disease, aortic stenosis, and severe peripheral vascular disease (such as a history of arteriosclerosis), and the researchers have determined that they are not suitable to participate in this trial.
- Suffering from serious heart diseases, including but not limited to unstable angina, cerebrovascular accidents or transient ischemic stroke (within 6 months before screening), myocardial infarction (within 6 months before screening), New York Heart Association (NYHA) classification e III, congestive heart failure, severe arrhythmia with poor drug control, requiring mechanical maintenance (such as pacemakers), placing heart stents or abnormal results of echocardiography and/or 12 lead electrocardiogram during screening, has clinical significance.
- Patients with hypertension have poor blood pressure control (SBP e 160mmHg and/or DBP e 100mmHg), and cannot discontinue long-term antihypertensive drugs such as angiotensin-converting enzyme inhibitors/angiotensin II receptor antagonists and potassium sparing diuretics 10 hours before surgery, and the researchers have determined that they are not suitable to participate in this trial.
- Individuals with a history of liver cirrhosis or liver dysfunction during screening and deemed unsuitable for surgery by researchers: AST or ALT\>2 times the upper limit of normal values; Albumin level\<35 g/L; Blood bilirubin is greater than 1.5 times the upper limit of normal value.

... and 19 more (see full listing online)

Locations (1 total)

Third Xiangya Hospital of Central South University, Changsha, Hunan, China