

Oral Hygiene and Prophylactic Antibiotics to Prevent Intracerebral Hemorrhage Associated Pneumonia

NCT07311343

Status	RECRUITING
Phase	Phase 4
Sponsor	Beijing Tiantan Hospital
Enrollment	440 participants

Key Eligibility Criteria

Inclusion (8)

- Age 18-80 years old;
- Spontaneous intracerebral hemorrhage;
- Supratentorial intracerebral hemorrhage (ICH);
- Hematoma volume \leq 30 ml (calculated by ABC/2 method);
- Glasgow Coma Scale score \geq 9 at randomization;

... and 3 more (see full listing online)

Exclusion (13)

- Secondary intracerebral hemorrhage, such as that resulting from cerebral aneurysms, cerebral arteriovenous malformations, brain tumors, cerebral venous system thrombosis, antithrombotic therapy (antiplatelet, anticoagulant therapy, etc.), hemorrhagic transformation after cerebral infarction, hematological diseases, etc.
- The patient's clinical symptoms and signs suggest signs of brain herniation, such as progressive decline in consciousness level, weakened or absent pupillary light reflex.
- Obvious signs of pneumonia already exist, such as fever, persistent cough or yellow purulent sputum, and imaging examinations (chest X-ray or chest CT) suggest signs of pneumonia; two consecutive measurements of body temperature \geq 37.5 , or one measurement of body temperature \geq 38.0 .
- A history of severe cardiovascular disease, meeting any of the following: 1) Heart failure (New York Heart Association functional class \geq III); 2) Unstable angina within 3 months; 3) Any supraventricular or ventricular arrhythmia requiring treatment; 4) Prolonged QTc interval considered clinically significant by the investigator (reference range: \leq 450ms for men, \leq 470ms for women) (Note: QTc interval must be calculated according to Fridericia's formula); 5) Complete atrioventricular block and left or right bundle branch block requiring treatment; 6) Acute myocardial infarction or interventional treatment within 1 month; high-risk patients with chronic arrhythmia, such as sick sinus syndrome, second or third-degree atrioventricular block, bradycardia-related syncope without pacemaker installation, etc.
- Diagnosed with severe active liver disease, such as acute hepatitis, chronic active hepatitis, liver cirrhosis, etc.; or ALT or AST \geq 3 times the upper limit of normal.

... and 8 more (see full listing online)

Locations (1 total)

Beijing Tiantan Hospital, Beijing, Beijing Municipality, China

<https://clinicaltrials.gov/study/NCT07311343>

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