

Hemorrhagic Brainstem Cavernous Malformations Treatment With Sirolimus: a Single Centre, Randomized, Placebo-controlled Pilot Trial

NCT06091332

Status	RECRUITING
Phase	Phase 2
Sponsor	Huashan Hospital
Enrollment	75 participants

Key Eligibility Criteria

Inclusion (5)

- Age 18-65 years, any gender;
- Patients who have experienced their first symptomatic BSCM ICH within the six months before randomisation;
- Diagnosed with solitary BSCM through T2, GRE/T2*, or SWI MR imaging;
- ICH within or around the BSCM confirmed by CT /MR;
- Capable of signing an informed consent form with the accompaniment and understanding of a guardian.

Exclusion (14)

- Cancer history;
- Pregnancy or lactation;
- Sirolimus/starch allergy;
- Modified Rankin Scale (mRS) score 5, respiratory failure or currently severe bleeding requiring life support treatment;
- Abnormal liver and/or kidney function (transaminase levels greater than 50, creatinine greater than 110), abnormal white blood cell/platelet counts (white blood cell count below 3.5 or above 9.5 x 10⁹/L or exceeding normal values, platelet count below 100 or above 300);

... and 9 more (see full listing online)

Locations (2 total)

Huashan Hospital, Fudan University, Shanghai, Shanghai Municipality, China
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