Cerebral Venous Thrombosis Cohort Study in China Mainland

**STUDY DESCRIPTION**

**Brief Summary**

This study was aimed to reveal the clinical features, natural history of the diseases and current therapeutic situations of cerebral venous thrombosis (CVT) in China mainland. Blood samples and cerebrospinal fluid samples will be collected after recruitment to reveal the pathological mechanisms of CVT and identify the biomarkers for CVT.

**Condition or Disease:**
- Cerebral Venous Sinus Thrombosis
- Deep Cerebral Vein Thrombosis
- Cortical Vein Thrombosis

**Intervention/treatment:**
- Phase: N/A

**DETAILED DESCRIPTION**

cerebral venous thrombosis (CVT) is caused by a clot in the cerebral vein, which resulted in an obstruction of the blood outflow. CVT mainly includes cerebral venous sinus thrombosis, deep cerebral vein thrombosis and cortical vein thrombosis. However, the epidemiological features of CVT in China mainland remained obscure. This study was aimed to establish a multicenter cohort recruiting patients with CVT across 31 provinces and municipalities in China mainland. Clinical features, natural history of the diseases and current therapeutic situations will be analyzed to reveal the epidemiological features of CVT. Blood samples and cerebrospinal fluid samples will be collected after recruitment to reveal the pathological mechanisms of CVT and identify the biomarkers for CVT. Patients will be followed-up at 1, 3, 6, 12 months from baseline to evaluate the clinical prognosis and therapeutic outcomes.

**STUDY DESIGN**

**Study Type:** Observational
**Estimated Enrollment:** 3000 participants
**Intervention Model:** N/A
**Masking:** N/A
**Primary Purpose:** N/A
**Observational Model:** Cohort
**Time Perspective:** Prospective

**Official Title:** Cerebral Venous Thrombosis Cohort Study in China Mainland

**Estimated Study Start Date:** June 2019
**Estimated Primary Completion Date:** May 2028
**Estimated Study Completion Date:** May 2029

**OUTCOME MEASURES**

**Primary Outcome Measures:**
- 1. Death rate [Time Frame: 1 year from baseline]
- 2. Functional independence [Time Frame: 1 year from baseline]
- 3. Recurrence of cerebral venous sinus thrombosis, deep cerebral venous thrombosis and cortical vein thrombosis [Time Frame: 1 year from baseline]
- 4. Incidence of hemorrhagic complication [Time Frame: 1 year from baseline]
- 5. Incidence of sinus wall rupture [Time Frame: 1 year from baseline]
- 6. Incidence of acute ischemic stroke [Time Frame: 1 year from baseline]
- 7. Incidence of acute myocardial infarction [Time Frame: 1 year from baseline]
- 8. Incidence of pulmonary embolism [Time Frame: 1 year from baseline]
- 9. Incidence of deep venous thrombosis [Time Frame: 1 year from baseline]

**Secondary Outcome Measures:**
- 1. Incidence of epilepsy [Time Frame: 1 year from baseline]
- 2. Incidence of allergic reaction [Time Frame: 1 year from baseline]

**Biospecimen Retention:** Samples With DNA
DNA detection will be conducted in a random selection of 300 blood samples.

**ELIGIBILITY CRITERIA**

**Ages Eligible for Study:** (Child, Adult, Older Adult)
**Sexes Eligible for Study:** All
**Accepts Healthy Volunteers:** No
Criteria

Inclusion Criteria:
- Cerebral venous sinus thrombosis, deep cerebral vein thrombosis and cortical vein thrombosis diagnosed by digital subtraction angiography (DSA), magnetic resonance venography (MRV), computed tomography venography (CTV) or high-resolution magnetic resonance imaging (HR-MRI).

Exclusion Criteria:
- None of the patient, trustee or immediate family members signed the informed consent.

CONTACTS AND LOCATIONS

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Locations

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MORE INFORMATION

Responsible Party: Capital Medical University
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Other Study ID Numbers: CVT-China
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Studies a U.S. FDA-regulated Drug Product: No
Studies a U.S. FDA-regulated Device Product: No

Keywords provided by Capital Medical University:
- Cerebral venous sinus thrombosis
- Deep cerebral vein thrombosis
- Cortical vein thrombosis
- Cohort study Real world evidence
- Observational study
- China mainland
- Cerebral venous system thrombosis

Additional relevant MeSH terms:
- Sinus Thrombosis, Intracranial Thrombosis
- Venous Thrombosis
- Embolism and Thrombosis
- Vascular Diseases
- Cardiovascular Diseases
- Intracranial Thrombosis
- Intracranial Embolism and Thrombosis
- Cerebrovascular Disorders
- Brain Diseases
- Central Nervous System Diseases
- Nervous System Diseases
- Thromboembolism