

# INPLASY PROTOCOL

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**Review Stage at time of this submission:** The review has not yet started.

**Conflicts of interest:** No.

## Comparison of hemostatic agents in patients with spontaneous intracerebral hemorrhage: a protocol for a network meta-analysis

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**Review question / Objective:** Which hemostatic drug has the best effect on the prevention of hematoma expansion and neurological deterioration in spontaneous intracerebral hemorrhage patients?

**Condition being studied:** Spontaneous intracerebral hemorrhage (sICH) is a serious stroke subtype. The effective therapies for patients with sICH are still unclear, and the role of hemostatic agents in sICH is still unclear. Although some studies have shown that hemostatic agents could benefit patients with sICH, different hemostatic drugs have different effects on patients with Spontaneous intracerebral hemorrhage, and which hemostatic drug has the best effect on the prevention of hematoma expansion (HE) and neurological deterioration in Spontaneous intracerebral hemorrhage patients remains unclear. To better understand the effects of hemostatic agents in patients with sICH, it is necessary to carry out a network meta-analysis to comprehensively compare the effects of different hemostatic agents.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 September 2020 and was last updated on 16 September 2020 (registration number INPLASY202090068).

### INTRODUCTION

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**Condition being studied:** Spontaneous intracerebral hemorrhage (sICH) is a serious stroke subtype. The effective therapies for patients with sICH are still unclear, and the role of hemostatic agents in sICH is still unclear. Although some studies have shown that hemostatic agents could benefit patients with sICH, different

hemostatic drugs have different effects on patients with Spontaneous intracerebral hemorrhage, and which hemostatic drug has the best effect on the prevention of hematoma expansion (HE) and neurological deterioration in Spontaneous intracerebral hemorrhage patients remains unclear. To better understand the effects of hemostatic agents in patients with sICH, it is necessary to carry out a network meta-analysis to comprehensively compare the effects of different hemostatic agents.

## METHODS

**Participant or population:** Adult sICH patients diagnosed by CT or MRI will be included in this study. Studies on the following conditions will not be included: secondary intracerebral hemorrhage, subarachnoid hemorrhage, primary intraventricular hemorrhage or ischemic stroke.

**Intervention:** Studies comparing at least two different hemostatic agents among the following will be included in this study: aminocaproic acid, tranexamic acid, aprotinin, recombinant activated factor VII, and hemocoagulase.

**Comparator:** At least two different hemostatic agents among the following will be included in this study: aminocaproic acid, tranexamic acid, aprotinin, recombinant activated factor VII, and hemocoagulase.

**Study designs to be included:** Randomized controlled trials and nonrandomized controlled studies will be included in this study. Case reports, case series and reviews will not be included in this study.

**Eligibility criteria:** Type of patients Adult sICH patients diagnosed by CT or MRI will be included in this study. Studies on the following conditions will not be included: secondary intracerebral hemorrhage, subarachnoid hemorrhage, primary intraventricular hemorrhage or ischemic stroke. Type of studies RCTs and nonrandomized controlled studies will be included in this study. Case reports, case

series and reviews will not be included in this study. Type of interventions Studies comparing at least two different hemostatic agents among the following will be included in this study: aminocaproic acid, tranexamic acid, aprotinin, rFVIIa, and hemocoagulase. Types of outcomes The primary outcome will be incidence of HE. HE will be evaluated by the imaging index threshold of each study. The secondary outcome will be the functional outcome at the end of follow-up. Functional outcome will be categorized as good or poor according to the scale and threshold in each study.

**Information sources:** We will conduct the literature search for the related RCTs and nonrandomized controlled studies until September 2020 in the following databases: PubMed, Embase, Scopus, Web of Science, the Cochrane Library, CNKI, VIP and Wanfang.

**Main outcome(s):** The primary outcome will be incidence of HE. HE will be evaluated by the imaging index threshold of each study. The secondary outcome will be the functional outcome at the end of follow-up. Functional outcome will be categorized as good or poor according to the scale and threshold in each study.

**Quality assessment / Risk of bias analysis:** The quality of all RCTs will be evaluated with the Cochrane Collaboration tool. The quality of all nonrandomized controlled studies will be assessed by the Newcastle-Ottawa Scale. Two authors will independently conduct quality evaluations, and any controversy will be addressed by discussion with another author.

**Strategy of data synthesis:** If quantitative analysis cannot be carried out, the results will be described narratively. When quantitative analysis is feasible, we will conduct all of the following statistical analyses by STATA V.14 (StataCorp, College Station, Texas, USA).

**Subgroup analysis:** We will perform subgroup analyses, if possible, according to age, sex, race, Glasgow Coma Scale

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score, baseline hematoma volume and hematoma location.

**Sensitivity analysis:** Sensitivity analysis, by eliminating each study, will be used to test whether the results are stable.

**Country(ies) involved:** China.

**Keywords:** Hematoma expansion; hemostatic agents; spontaneous intracerebral hemorrhage; outcome.

**Contributions of each author:**

Author 1 - Yujian Li.

Author 2 - Jun Zheng.

Author 3 - Huiqing Zhou.

Author 4 - Xiang Yang.

Author 5 - Hao Li.