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Tranexamic acid for spontaneous intracerebral hemorrhage: Updated meta-analysis following STOP-MSU trial

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Piloting of the study selection process.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202450025

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 May 2024 and was last updated on 07 May 2024.

INTRODUCTION

Review question / Objective Does tranexamic acid affect the clinical outcome of spontaneous intracerebral hemorrhage ?

Condition being studied Tranexamic acid, an antifibrinolytic agent, is thought to potentially mitigate hematoma expansion following spontaneous intracerebral hemorrhage (ICH). Numerous previous studies have explored the efficacy of administering tranexamic acid to patients with spontaneous ICH, with meta-analysis suggesting a significant reduction in the risk of intracranial hemorrhage growth and poor functional outcome. However, the recent STOP-MSU trial reported that intravenous tranexamic acid did not decrease hematoma growth when administered within 2 hours of symptom onset in patients with intracerebral hemorrhage. Furthermore, the trial found no discernible effects on other imaging endpoints, functional outcomes, or safety parameters. Given these divergent findings, we intend to conduct an updated meta-analysis that incorporates the results of the STOP-MSU trial along with relevant previous randomized controlled trials (RCTs). This updated meta-analysis aims to provide clearer insights into the efficacy of tranexamic acid in spontaneous ICH.

METHODS

Participant or population Patients with spontaneous intracerebral hemorrhage.

Intervention Tranexamic acid.

Comparator Placebo.

Study designs to be included Randomized controlled trials.

Eligibility criteria 1. Trials investigating effect of administration of tranexamic acid in spontaneous ICH 2. Trails reporting at least one outcome reported in the STOP-MSU trial.

Information sources The information will be extracted from full-text articles obtained from electronic databases.

Main outcome(s) 1. risk of hematoma expansion 2. risk of poor clinical outcome 3. risk of mortality within 90 days 4. risk of thromboembolic event.

Quality assessment / Risk of bias analysis Quality assessment will be performed using revised tool to assess risk of bias in randomized trials (RoB 2.0).

Strategy of data synthesis Meta-analyses were performed using R software with the "meta" package (Viechtbauer, 2010). Relevant outcomes were extracted from the included studies and pooled using a random-effects model with the Mantel–Haenszel method. The pooled odds ratios (ORs) were presented with 95% confidence intervals (CIs).

Subgroup analysis Subgroup analysis will be performed based on different timing of tranexamic acid administration.

Sensitivity analysis Leave-one-out meta-analysis will be performed for sensitivity analysis.

Country(ies) involved Taiwan.

Keywords tranexamic acid, spontaneous intracerebral hemorrhage, meta-analysis.

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