INPLASY PROTOCOL

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Conflicts of interest:
None declared.

The efficacy and safety of argatroban in the treatment of acute ischemic stroke: a systematic review and meta-analysis

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Review question / Objective: **Our objective is to analyze the efficacy and safety of agatroban in acute ischemic stroke.**
Condition being studied: **Acute ischemic stroke.**
Eligibility criteria: **Randomized controlled trials (RCTs), non-RCTs and cohort studies were selected for review if they met the following criteria: (1) included patients with confirmed AIS; (2) compared the efficacy and/or safety between treatment with and without tirofiban; and (3) reported outcomes including at least one of the following: NIHSS improvement, early neurological deterioration, modified Rankin Scale (mRS) at 3 months, symptomatic intracranial hemorrhage (sICH), any ICH, systemic hemorrhage, mortality.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 April 2022 and was last updated on 15 April 2022 (registration number INPLASY202240088).

INTRODUCTION

Review question / Objective: **Our objective is to analyze the efficacy and safety of agatroban in acute ischemic stroke**

Rationale: **Up to now, anticoagulants are not recommended as the first choice of treatment for acute ischemic stroke (AIS). However, many studies have shown that early intravenous administration of agtroban can improve the functional prognosis of AIS patients with a low risk of bleeding. At present, it is still controversial whether argatroban should be recommended in the early phase of AIS. we intend to conduct a systematic review and**

meta-analysis on the efficacy and safety of agatroban in the treatment of AIS.

Condition being studied: Acute ischemic stroke.

METHODS

Search strategy: We searched PubMed, EMBASE, Cochrane Library, ClinicalTrials.gov (www.clinicaltrials.gov/), CNKI, VIP, Wanfang database using the search terms "argatroban", "stroke", "brain ischemia" et al. In addition, references from relevant published original articles were retrieved manually, and the corresponding author was contacted when necessary. The language of studies were limited to English and Chinese.

Participant or population: Acute ischemic stroke patients.

Intervention: Argatroban.

Comparator: Placebo or standard therapy for ischemic stroke without argatroban.

Study designs to be included: Randomized controlled studies, non-randomized controlled studies, and cohort studies.

Eligibility criteria: Randomized controlled trials (RCTs), non-RCTs and cohort studies were selected for review if they met the following criteria: (1) included patients with confirmed AIS; (2) compared the efficacy and/or safety between treatment with and without tirofiban; and (3) reported outcomes including at least one of the following: NIHSS improvement, early neurological deterioration, modified Rankin Scale (mRS) at 3 months, symptomatic intracranial hemorrhage (sICH), any ICH, systemic hemorrhage, mortality.

Information sources: PubMed, EMBASE, Cochrane Library, ClinicalTrials.gov (www.clinicaltrials.gov/), CNKI, VIP and Wanfang databases.

Main outcome(s): NIHSS improvement and 90-day modified Rankin Scale (mRS).

Additional outcome(s): early neurological deterioration, any ICH, systemic hemorrhage, mortality.

Data management: Two investigators retrieved the potential studies by title and abstract, and then reviewed the full article to identify the included studies according to the inclusion and exclusion criteria. The data will be extracted independently by two independent investigators.

Quality assessment / Risk of bias analysis: The Cochrane risk-of-bias assessment tool will be used to evaluate the potential sources of bias in the included RCTs; the methodological index for non-randomized studies (MINORS) will be used to evaluate non-RCTs; the Newcastle–Ottawa Scale will be used to evaluate the quality of cohort studies.

Strategy of data synthesis: The meta-analysis will be conducted using Review Manager (RevMan) version 5.4 . Pooled odds ratios (OR) and 95% confidence intervals (CIs) will be calculated according to the Mantel–Haenszel method with a fixed-effects or random-effects model according to the heterogeneity among the included studies.

Subgroup analysis: When substantial heterogeneity is confirmed, subgroup analyses and forest plots will be conducted to probe the source of heterogeneity.

Sensitivity analysis: Sensitivity will be performed to check the stability of the results by removing each study at one time in a series of meta-anal-yses.

Language: English and Chinese.

Country(ies) involved: China.

Keywords: ischemic stroke; argatroban; meta-analysis.

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