INPLASY PROTOCOL

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Support: **None.**

Review Stage at time of this submission: **Preliminary searches.**

Conflicts of interest:
None declared.

The Efficacy and Safety of Novel Oral Anticoagulants in Pediatric Venous Thromboembolism Treatment and Prevention: systematic review and meta-analysis

Geng, Y[1*]; Meng, C[2*]; Gao, T[3*]; Li, SY[4]; Bi, L[5]; Wang, YT[6]; Zhang, P[7].

Review question / Objective: **We sought to conduct a systematic review and meta-analysis to evaluate the efficacy and safety of novel oral anticoagulants in pediatric venous thromboembolism treatment and prevention.**
Condition being studied: **Venous thromboembolism, Major bleeding, Major or clinically relevant non-major bleeding, All-cause death, Severe any event.**
Information sources: **We will search the references in the included trials and personal files. We will request advice from experts in the field. In addition, we will search associated articles from meetings, and contacted the authors of included trials, if need.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 December 2022 and was last updated on 16 December 2022 (registration number INPLASY2022120065).

*Yu Geng, Chang Meng and Tong Gao have contributed equally to this work.

INTRODUCTION

Review question / Objective: **We sought to conduct a systematic review and meta-analysis to evaluate the efficacy and safety of novel oral anticoagulants in pediatric venous thromboembolism treatment and prevention.**

Condition being studied: Venous thromboembolism, Major bleeding, Major or clinically relevant non-major bleeding, All-cause death, Severe any event.

METHODS

Participant or population: Patients with novel oral anticoagulants for venous thromboembolism treatment and prevention in pediatric.

Intervention: Novel oral anticoagulants or SOC (standard of care).

Comparator: Placebo.

Study designs to be included: The search strategy was RCTs or Prospective observational studies.

Eligibility criteria: (1) Patients with novel oral anticoagulants for venous thromboembolism treatment and prevention in pediatric. (2) outcomes Indicators: Venous thromboembolism, Major bleeding, Major or clinically relevant non-major bleeding, All-cause death, Severe any event, including one.

Information sources: We will search the references in the included trials and personal files. We will request advice from experts in the field. In addition, we will search associated articles from meetings, and contacted the authors of included trials, if need.

Main outcome(s): Venous thromboembolism, Major bleeding, Major or clinically relevant non-major bleeding, All-cause death, Severe any event.

Quality assessment / Risk of bias analysis: We evaluated the methodological quality of the individual studies using the Cochrane risk of bias tool for RCTs and using the Newcastle-Ottawa Scale for prospective observational studies.

Strategy of data synthesis: We will consider using the number of participants and Venous thromboembolism between different groups for analysis.

Subgroup analysis: We will analyze the literature data, and may not conduct subgroup analysis.

Sensitivity analysis: We conducted sensitivity analyses to investigate the influence of a single study on the overall pooled estimate of each predefined outcome.

Country(ies) involved: China.

Keywords: Novel Oral Anticoagulants; Pediatric; Venous Thromboembolism.

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