# **INPLASY** PROTOCOL

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**Review Stage at time of this** submission: Data extraction.

**Conflicts of interest:** None.

## **INTRODUCTION**

**Review question / Objective: The efficacy** and safety of proton pump inhibitors (PPIs), as compared with a placebo, gastroduodenal mucosal protective agents, or H2RAs, for the prevention of antiplatelet drug-associated peptic ulcers or gastrointestinal hemorrhage.

**Rationale:** Proton pump inhibitors (PPIs) significantly reduce the risk of peptic ulcers or gastrointestinal (GI) hemorrhage during antiplatelet therapy. However, concerns have been raised regarding the increased risk of GI complications and adverse cardiovascular events due to the PPI-clopidogrel interaction. This study

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The efficacy and safety of proton

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gastrointestinal hemorrhage: A

Tong, Y<sup>1</sup>; Qin, S<sup>2</sup>; Wu, Z<sup>3</sup>; He, Y<sup>4</sup>; Zhou, C<sup>5</sup>; Yang, P<sup>6</sup>.

Condition being studied: Upper gastrointestinal bleeding (UGIB) is a common medical emergency, with a reported mortality of 2-10%. Peptic ulcer is one of the most common cuases of upper gastrointestinal bleeding.

Information sources: PubMed, Embase, and Web of Science

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 December 2020 and was last updated on 14 December 2020 (registration number INPLASY2020120078).

aimed to evaluate the efficacy and safety of PPIs for the prevention of antiplatelet drugassociated peptic ulcers or GI hemorrhage.

Condition being studied: Upper gastrointestinal bleeding (UGIB) is a common medical emergency, with a reported mortality of 2-10%. Peptic ulcer is one of the most common cuases of upper gastrointestinal bleeding.

#### **METHODS**

Search strategy: We systematically searched PubMed, Embase, and Web of Science between inception and Dec 6, 2020, for studies that assessed the efficacy and safety of PPIs for antiplatelet drugassociated ulcers or GI hemorrhage.

Participant or population: Patients who reveive treatment with antiplatelet drugs.

Intervention: Proton pump inhibitors (PPIs).

**Comparator:** A placebo, gastroduodenal mucosal protective agents, or H2RAs.

Study designs to be included: Controlled trials.

Eligibility criteria: Eligible studies met the following criteria: (1) The design of the studies was a controlled trial. (2) Patients eligible for inclusion were adults (aged  $\geq$ 18 years) who used an antiplatelet drug (aspirin with or without clopidogrel) for at least two continuous weeks. (3) Intervention measures: Oral PPIs were used in the experimental group, and a placebo, gastroduodenal mucosal protective agents, or H2RAs were used in the control group. (4) Outcomes of studies: The incidence of antiplatelet drug-related peptic ulcers, GI hemorrhage, major adverse cardiovascular events (MACE), and diarrhea in the two groups was observed. (5) Only studies published in English were included.

Information sources: PubMed, Embase, and Web of Science.

Main outcome(s): ORs for the association between PPIs and the risk of peptic ulcers or gastrointestinal hemorrhage during antiplatelet therapy.

Quality assessment / Risk of bias analysis: Cochrane Collaboration Risk of Bias tool.

**Strategy of data synthesis: Cochrane** Collaboration Risk of Bias tool.

Subgroup analysis: A subgroup analysis was performed based on several control groups.

Sensibility analysis: We conducted a sensitivity analysis by sequentially omitting each study to analyze the effect of an individual study on the overall results.

Language: English.

Country(ies) involved: China.

Keywords: proton pump inhibitors, aspirin, clopidogrel, peptic ulcers, gastrointestinal hemorrhage.

#### **Contributions of each author:**

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