INPLASY PROTOCOL

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Support: **None.**

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

Conflicts of interest:
None.

Efficacy and safety of misoprostol for peptic ulcer disease: a systematic review and meta-analysis

Zeng, Z[1]; Xiao, N[2]; Ye, L[3]; Wu, Q[4].

Review question / Objective: **Is treatment of misoprostol efficacy and safety in adult patients with peptic ulcer disease?**
Condition being studied: **Peptic ulcer disease. Peptic ulcer disease is common, with some 10% of the population of Western countries likely to suffer a duodenal or gastric ulcer during their lifetime.**
Information sources: **All the studies will come from electronic databases. If we need more informations which is not include in the paper, we will contact with authors.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 06 July 2020 and was last updated on 06 July 2020 (registration number INPLASY202070019).

INTRODUCTION

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METHODS

Search strategy: 1 - Name all sources that will be used to identify studies for the systematic review; 2 - Search dates (from MEDLINE, EMBASE and The Cochrane Library); 3 - Restrictions on the search including language and publication period： There is no restriction of language on the search.EMBASE to April 2020, MEDLINE to April 2020, he Cochrane Library to April 2020.

Participant or population: All participants recruited in the trials analysed will be adults who had peptic ulcer diagnosed at endoscopy.

Intervention: Misoprostol.

Comparator: Placebo.

Study designs to be included: We will include randomised, placebo-controlled studies.

Eligibility criteria: It is a randomised, placebo-controlled studies. All participants recruited in the trials analysed will be adults who had peptic ulcer diagnosed at endoscopy.

Information sources: All the studies will come from electronic databases. If we need more informations which is not include in the paper, we will contact with authors.

Main outcome(s): Proportion of peptic ulcers healed after initial therapy.

Additional outcome(s): 1.Proportion of participants that achieved complete relief from symptoms of peptic ulcer. 2. Recording of adverse effects of the pharmacological interventions.

Quality assessment / Risk of bias analysis: Two review authors will assess the risk of bias for each study independently using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011) and resolved any disagreement by discussion. We will assess the risk of bias according to the following domains: 1. random sequence generation; 2. allocation concealment; 3. blinding of participants, personnel and outcome assessors; 4. incomplete outcome data; 5. selective outcome reporting; 6. other bias. We will grade each potential source of bias as high, low or unclear and provide a quote from the study report together with a justification for our judgement in the 'Risk of bias' table. We will summary the riskof bias judgements across different studies for each of the domains listed.

Strategy of data synthesis: We will combine risk ratios (RR) for binary outcomes. We will calculate the number needed to treat for an additional beneficial outcome(NNTB) or number needed to treat for an additional harmful outcome (NNTH) as the inverse of the risk difference from the meta analysis. For binary outcomes, such as peptic ulcer healing, peptic ulcer recurrence and absence of symptoms, we will express the impact of interventions as risk ratios (RR) together with 95% confidence intervals (CI). We will analyse the data for gastric ulcer and duodenal ulcer, and for short- and long-term treatment, separately.

Subgroup analysis: Where significant ($P < 0.1$) heterogeneity is detected, we will investigate possible explanations informally, and summarise the data using a random-effects analysis.

Sensibility analysis: We will conduct a sensitivity analysis using data from trials assessed as having low risk of selection bias.

Language: We will exclude studies that were not written in English.

Country(ies) involved: China.

Keywords: Systematic review; meta-analysis; misoprostol; peptic ulcer.

Dissemination plans: In addition to producing a report for the funders of this review, which will be made available free of

charge on their website, a paper will be submitted to a leading journal in this field. Furthermore, should the findings of the review warrant a change in practice, a one page summary report will be prepared and sent to lead clinicians and healthcare professionals in the National Health Service.

Contributions of each author:

Author 1 - Zheng Zeng - Zheng Zeng initiated and designed the study. Zheng Zeng participated in study design. Zheng Zeng drafted the manuscript.
Author 2 - Nanping Xiao - Nanping Xiao participated in study design.
Author 3 - Li Ye - Li Ye participated in study design.
Author 4 - Qin Wu - Qin Wu participated in study design.