INPLASY PROTOCOL

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None declared.

Effectiveness and Safety of Chinese Medicine Combined with Omeprazole in the Treatment of Gastric Ulcer: A protocol for systematic review and meta-analysis

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Review question / Objective: In order to further clarify its clinical application value, this study adopts the methods of systematic review and Meta analysis to comprehensively evaluate the effectiveness and safety of traditional Chinese medicine combined with omeprazole in the treatment of GU, and provide evidence-based basis for its rational use in clinical practice.

Information sources: Computer search of PubMed, Embase, Cochrane Library, CNKI, VIP and Wanfang data. Literature search is limited to Chinese and English. The search time range is from the establishment of the database to April 7, 2021. The search strategy uses a combination of subject terms and free words to search. In order to avoid omissions, the search scope includes subject terms, keywords or full text.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 April 2021 and was last updated on 08 April 2021 (registration number INPLASY202140048).

INTRODUCTION

Review question / Objective: In order to further clarify its clinical application value, this study adopts the methods of systematic review and Meta analysis to comprehensively evaluate the effectiveness and safety of traditional Chinese medicine combined with omeprazole in the treatment of GU, and provide evidence-based basis for its rational use in clinical practice.

Condition being studied: Gastric ulcer (GU) is a chronic digestive system disease with a high clinical incidence and recurrence rate. The clinical manifestations are upper

abdominal pain, abdominal distension, belching and acid reflux. In severe cases, it may be accompanied by hematemesis and melena, or even may be complications such as gastric perforation, gastric bleeding, canceration, etc., have a serious impact on the patient's health and quality of life.The treatment principle is to protect the gastric mucosa and inhibit the secretion of gastric acid. In the clinical treatment of GUs, acid suppression is the main measure. The commonly used drug omeprazole is a proton pump inhibitor, but in clinical practice, it has been found that the effect of omeprazole alone is not very satisfactory.At present, Chinese medicine plays an indispensable role in treating GU and preventing recurrence due to its unique advantages. In terms of diagnosis and treatment, different physicians have different ideas of syndrome differentiation, different treatment methods, and a hundred schools of thought, which greatly enriched the theory of traditional Chinese medicine for the treatment of GU.

METHODS

Participant or population: Patients who are clinically diagnosed with gastric ulcer through digestive endoscopy are not limited by gender, age, and course of disease. Participants with serious underlying diseases will be excluded.

Intervention: The experimental group was treated with Chinese medicine decoction combined with omeprazole.

Comparator: The control group was treated with omeprazole.

Study designs to be included: The type of literature research is RCTs.

Eligibility criteria: (1) Type of study. Only randomized controlled trials (RCT) will be included, regardless of whether they are blinded or not, are limited to Chinese and English. (2) Study participants: Patients who are clinically diagnosed with gastric ulcer through digestive endoscopy are not limited by gender, age, and course of disease. Participants with serious

underlying diseases will be excluded. (3) Types of interventions and comparators. The experimental group was treated with Chinese medicine decoction combined with omeprazole, and the control group was treated with omeprazole. (4) Outcome indicators:Effective rate: Effective rate (%) = (number of cured cases + number of markedly effective cases + number of effective cases) / total number of cases × 100%. Incidence rate of adverse reactions. Recurrence rate of gastric ulcer bleeding. Time required for clinical symptom improvement. Ulcer surface healing. According to the results of gastroscopy, the clinical efficacy of patients was evaluated.

Information sources: Computer search of PubMed, Embase, Cochrane Library, CNKI, VIP and Wanfang data. Literature search is limited to Chinese and English. The search time range is from the establishment of the database to April 7, 2021. The search strategy uses a combination of subject terms and free words to search. In order to avoid omissions, the search scope includes subject terms, keywords or full text.

Main outcome(s): Effective rate:Effective rate (%) = (number of cured cases + number of markedly effective cases + number of effective cases) / total number of cases × 100%. Incidence rate of adverse reactions. Recurrence rate of gastric ulcer bleeding. Time required for clinical symptom improvement. Ulcer surface healing. According to the results of gastroscopy, the clinical efficacy of patients was evaluated. The cure is that the gastroscopy shows that the ulcer has completely disappeared and the gastric mucosa has no inflammation; the obvious effect is that the gastroscopy shows that the area of the ulcer is reduced by >70%, and the inflammation of the gastric mucosa is significantly reduced; the effective is that the gastroscopy shows The area of the ulcer is reduced by 10% to 70%, and the inflammation of the gastric mucosa is reduced. Ineffective, the gastroscopy shows that the area of the ulcer is reduced or increased by less than 10%, and the

inflammation of the gastric mucosa is not reduced, and the disease is even worse.

Quality assessment / Risk of bias analysis: According to the RCT bias risk evaluation method recommended by Cochrane Handbook,10 the quality evaluation is carried out: random allocation; allocation hiding; blinding to the research objects and treatment plan implementers; evaluation of outcome indicators Blind method is used; report the result data completely; report the research results selectively; other sources of bias. Two reviewers evaluated each article based on the above items, including three levels of "low risk of bias", "unknown risk of bias" and "high risk of bias". For each included literature, two reviewers independently conduct methodological quality evaluation, and if there is a disagreement, they will discuss and resolve with the third person.

Strategy of data synthesis: The RevMan 5.3 software provided by the Cochrane Collaboration was used for statistical analysis.12 Enumeration data uses Risk ratio (RR) as the effect indicator, measurement data uses the mean difference (MD) as the effect indicator, and each effect size is given its point estimate and 95% confidence interval (CI) . The heterogeneity test of the research results adopts the $\chi 2$ test. If the homogeneity is good (P>.1, I2<50%), the fixed-effects model is used for analysis; if the heterogeneity is large (P50%), the heterogeneity is performed first sexual source analysis, and then subgroup analysis or sensitivity analysis based on possible heterogeneity factors, that is, random effects model and fixed effects model are used. Whether there is a significant difference between the conclusions of the two different models for calculating the combined value of the effect. If the Z values are not much different and the P values are both meaningful, then the conclusions are robust and can eliminate heterogeneity. If the heterogeneity still exists, but the trials have clinical homogeneity, the random effects model is used to combine the effect size. However, if there is obvious clinical heterogeneity between the studies, they will not be merged, and only a descriptive analysis will be performed.

Subgroup analysis: If there is significant clinical and statistical heterogeneity (P50%), subgroup analysis should be performed in order to further the source of heterogeneity. Group the influencing factors such as the type of intervention, age, race, etc., and observe the heterogeneous results.

Sensitivity analysis: Carry out sensitivity analysis to test the reliability and stability of the system evaluation results, and look for the heterogeneity of causality. The method to solve this problem is to exclude the changes in the observation of heterogeneous results one by one from the included studies, to get rid of research bias or to remove the high risk of certain special studies.

Country(ies) involved: China.

Keywords: Chinese Medicine, Gastric Ulcer, Protocol, Systematic review.

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