INPLASY PROTOCOL

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

Conflicts of interest:
None declared.

Acupuncture for Peptic Ulcer: protocol for a systematic review and meta-analysis

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Review question / Objective: This study will comprehensively search the literature to further systematically evaluate the efficacy and safety of acupuncture in the treatment of peptic ulcer. Provide the latest evidence-based medical evidence for clinical prevention and treatment of such diseases.

Condition being studied: Peptic ulcer refers to acid peptic injury of the digestive tract, resulting in mucosal break reaching the submucosa. Peptic ulcers are usually located in the stomach or proximal duodenum, but they can also be found in the oesophagus or Meckel's diverticulum. The typical clinical manifestations of peptic ulcer are chronic, periodic and rhythmic upper abdominal pain. Lifetime prevalence of peptic ulcer disease in the general population has been estimated to be about 5–10%, and incidence 0·1–0·3% per year. However, the incidence of peptic ulcer disease may now be lower than these estimates worldwide, especially in high-income countries. Although this disease does not pose a fatal danger, it will greatly reduce the patient's quality of life. There are many ways to treat peptic ulcers now. Acupuncture has a long history of treating upper abdominal pain. Some modern clinical studies also show that acupuncture has a significant effect on peptic ulcer. Compared with general medical treatments, acupuncture is safer and has no side effects.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 March 2021 and was last updated on 18 March 2021 (registration number INPLASY202130062).

INTRODUCTION

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METHODS

Participant or population: This study will be included in patients with clinically diagnosed peptic ulcer (including gastric ulcer, duodenal ulcer) without peptic ulcer bleeding and postoperative treatment. No age, sex or race restrictions.

Intervention: The intervention measures of the experimental group mainly include any form of acupuncture therapy to treat peptic ulcers, such as scalp acupuncture, ear acupuncture, electric acupuncture and so on. However, comparative studies on the efficacy of different acupuncture will be excluded. The control group includes any form of treatment, such as sham acupuncture and medication. It also includes treatment, routine care, and other routine treatments.

Comparator: All cases included in the trial are patients with peptic ulcer, and there are no restrictions on age, gender and race.

Study designs to be included: A randomized controlled trial (RCT) study on peptic ulcer, published in any language.

Eligibility criteria: This study will include a randomized controlled trial (rct) comparing acupuncture-related therapies with a control group. If the trial specifies a "randomization" phase, it will be considered a randomized study, and blinding is not restricted. We will exclude non-randomized controlled trials. There are no language restrictions in this study.

Information sources: We will search PubMed, Embase, the Cochrane Central Register of Controlled Trials (Central), China Biomedical Literature Database (CBM), China National Knowledge Infrastructure (CNKI), Chinese Science and Technology Journal Database (VIP), Wanfang Database (Wanfang Data) and other electronic databases.

Main outcome(s): Total effective rate, Helicobacter pylori (H.pylori) conversion rate.

Additional outcome(s): 1. gastroscopy examination of ulcer area healing rate 2. Ulcer recurrence rate 3. Recurrence rate 4. Quality of life 5. The incidence of adverse events.

Quality assessment / Risk of bias analysis: Two reviewers performed rigorous methodological quality evaluation of the included studies with reference to the Cochrane Collaboration Bias Risk Assessment Tool for the extracted methodological features.

Strategy of data synthesis: We will use RevMan software (version 5.3.5) and R software (version 3.6.1) for data statistical analysis. We will conduct an analysis to provide an estimate of the effect on binary data and continuous data, using a 95% confidence interval. For binary data we will use the risk ratio (RR). For continuous data we will use mean difference (MD). In addition, we will explore heterogeneity before meta-analyzing the results. A standard chissquare test with a

significance level of P <0.10 was used to detect heterogeneity. The I2 statistic will be used to quantify the inconsistency of various studies and evaluate the impact of heterogeneity on meta-analysis. For binary classification results, the Mantel-Haenszel method will be used, and for continuous results, DerSimonian and Laird inverse variance methods will be used. We will also use a random effects model to pool the data.

Subgroup analysis: After data collection, if there are a sufficient number of studies, we will conduct a subgroup analysis to assess the heterogeneity between the included trials. The analysis will include the types of acupuncture observation group and control group, such as acupuncture and sham acupuncture (including non-penetrating acupuncture). In addition, we will also consider including the analysis of other subgroups reported in the study, but we will pay special attention to the possible selective reporting bias when using any such subgroups in our review.

Sensitivity analysis: Sensitivity analysis will be conducted by excluding any one or more selection, wear, or high risk of detection bias into the study. In the analysis process, we will eliminate the lower quality trials, and then repeat the meta-analysis.

Country(ies) involved: China.

Keywords: Peptic ulcer, acupuncture, Systematic review, Meta-analysis, protocol.

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