

INPLASY PROTOCOL

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**Review Stage at time of this
submission:** Preliminary
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Conflicts of interest:

There is no conflict of
interest.

Efficacy and safety of TCM therapies combined with hyperthermic intraperitoneal chemotherapy for peritoneal metastasis of gastric cancer: A protocol for systematic review and meta-analysis

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Review question / Objective: The aim of this meta-analysis of randomized controlled trials is to evaluate the efficacy and safety of Traditional Chinese Medicine therapies combined with HIPEC in the treatment for peritoneal metastasis of gastric cancer.

Condition being studied: Gastric cancer (GC) has high incidence and mortality worldwide, and peritoneal metastasis is a primary cause of mortality in patients. Hyperthermic intraperitoneal chemotherapy (HIPEC) is a feasible and effective treatment. Traditional Chinese Medicine (TCM) therapies have been combined with HIPEC for certain therapeutic advantages, but there is a lacking of evidence of evidence-based medicine. Therefore, we provide a protocol to evaluate the efficacy and safety of TCM therapies combined with HIPEC in the treatment for peritoneal metastasis of GC.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 December 2020 and was last updated on 08 December 2020 (registration number INPLASY2020120048).

INTRODUCTION

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and safety of Traditional Chinese Medicine therapies combined with HIPEC in the treatment for peritoneal metastasis of gastric cancer.

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METHODS

Search strategy: We will search, with no time restrictions, the following databases for relevant literature: The Cochrane Library, MEDLINE, Embase, Chinese BioMedical Database (CBM), China National Knowledge Infrastructure (CNKI), Chinese VIP Information (VIP), Wangfang Database. The search string will be built as follows: (Traditional Chinese Medicine [MeSH]) AND (Gastric cancer [MeSH]) AND (Peritoneal metastasis [MeSH]) AND (Hyperthermic intraperitoneal chemotherapy[MeSH]).

Participant or population: Patients (adults over 18 years old) were histologically confirmed peritoneal metastasis of gastric cancer, and TNM classification was based on National Comprehensive Cancer Network.

Intervention: TCM therapy combined with HIPEC. TCM therapy interventions, including TCM decoction and Chinese patent medicine.

Comparator: Hyperthermic intraperitoneal chemotherapy alone.

Study designs to be included: Only randomized controlled trials (RCTs) will be included.

Eligibility criteria: Regardless of the blind method and language, only randomized

controlled trials (RCTs) will be included. RCTs regarding TCM therapies plus HIPEC for peritoneal metastasis of gastric cancer.

Information sources: Electronic databases: The Cochrane Library, MEDLINE, Embase, Chinese BioMedical Database (CBM), China National Knowledge Infrastructure (CNKI), Chinese VIP Information (VIP), Wangfang Database.

Main outcome(s): Disease-free survival (DFS); Overall survival (OS).

Additional outcome(s): Adverse effects; Change in symptoms as measured with validated questionnaires; Quality of life as measured using a validated questionnaire.

Quality assessment / Risk of bias analysis: Two reviewers will evaluate risk of bias in included studies based on the Cochrane collaboration's risk of bias assessment tool. If there are divided questions or opinions between 2 investigators will asking for a help from a senior researcher. Seven items are included: Random sequence generation, allocation concealment, subjects and researchers blinded, outcome evaluation of blind method, the result data are incomplete and selective report results and other sources of bias and classified as "low," "high," or "unclear".

Strategy of data synthesis: We will use RevMan 5.3 software (The Cochrane Collaboration, Oxford, England) to calculate for data synthesis. If there no obvious statistical heterogeneity among the trails included, we will apply fixed effects model to perform in the analysis. However, the random effects model will be used, when apparent clinical heterogeneity among the trails included. Meanwhile, subgroup or sensitivity analysis will be conducted. $\alpha=0.05$ will be deemed statistically significant.

Subgroup analysis: Subgroup analysis will be conducted according to sex, locations, histologic diagnosis, duration of TCM

therapies, timing of TCM therapies, and chemotherapy regimens.

Sensibility analysis: Sensitivity analysis will be conducted to explore the quality of studies of the document following sample size, the outcome of missing data, and methodological quality.

Country(ies) involved: China.

Keywords: gastric cancer; peritoneal metastasis; hyperthermic intraperitoneal chemotherapy; complementary and alternative medicine; Traditional Chinese Medicine; meta-analysis; systematic review; protocol

Contributions of each author:

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