INPLASY PROTOCOL

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Conflicts of interest:
The authors declare that they have no competing interests.

Chinese patent medicine (Jinlong capsule) for gastric cancer: protocol for a systematic review and meta-analysis

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Review question / Objective: **Is Jinlong Capsule (JLC) effective and safety for patients with advanced Gastric cancer (GC)?**
Condition being studied: **Jinlong Capsule.**
Information sources: Eight electronic databases including Cochrane Library, PubMed, Web of Science (WOS), Excerpt Medica Database (Embase), Chinese Biomedical Literature Database (CBM), China National Knowledge Infrastructure (CNKI), China Scientific Journal Database (VIP) and Wanfang Database will be systematically searched for eligible studies from their inception to January 2020. Language is limited with English and Chinese.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 April 2020 and was last updated on 17 April 2020 (registration number INPLASY202040105).

INTRODUCTION

Review question / Objective: **Is Jinlong Capsule (JLC) effective and safety for patients with advanced Gastric cancer (GC)?**

Rationale: **Jinlong Capsule (JLC) has been widely applied as a promising adjunctive drug for Gastric cancer (GC). However, the exact effects and safety of JLC have yet to be systematically investigated. We aimed to summarize the efficacy and safety of JLC for the treatment of advanced GC through the meta-analysis, in order to provide scientific reference for the design of future clinical trials.**

Condition being studied: Jinlong Capsule.

METHODS

Search strategy: To perform a comprehensive and focused search, experienced systematic review researchers will be invited to develop a search strategy. The plan searched terms are as follows: "gastric cancers" or "gastric neoplasm" or "gastric carcinoma" or "gastric tumor" or "stomach cancers" or "stomach neoplasm" or "stomach carcinoma" or "stomach tumor" or "GC" or "SC" and "Jinlong Capsule" or "JLC" et al. An example of search strategy for PubMed database shown in Table 1 will be modified and used for the other databases.

Participant or population: Patients must be cytologically or pathologically confirmed as having GC at a clinically advanced stage. There will be no limitations on age, gender, racial and region. Patients with other malignancies or non-primary GC are not included.

Intervention: In the experimental group, advanced GC patients must be treated with conventional treatment (including chemotherapy, radiotherapy, and targeted therapy) combined with JLC mediated therapy.

Comparator: In the control group, GC patient treated with the same conventional treatment as intervention group in the same original study.

Study designs to be included: All available RCTs that investigated the efficacy and safety of JLC-mediated therapy in patients diagnosed with advanced GC will be included.

Eligibility criteria: This study will include RCTs that compared the efficacy and safety of JLC with other treatments for patients with advanced GC. Articles without sufficient available data, non-comparative studies, non-RCTs, literature reviews, meta-analysis, meeting abstracts and case reports will be excluded.

Information sources: Eight electronic databases including Cochrane Library, PubMed, Web of Science (WOS), Excerpt Medica Database (Embase), Chinese Biomedical Literature Database (CBM), China National Knowledge Infrastructure (CNKI), China Scientific Journal Database (VIP) and Wanfang Database will be systematically searched for eligible studies from their inception to January 2020. Language is limited with English and Chinese.

Main outcome(s): The primary outcomes will be the therapeutic effects of treatment according to Response Evaluation Criteria in Solid Tumors 1.1 (RECIST Criteria 1.1). (a) Overall response rate (ORR) and disease control rate (DCR); (b) Overall survival (OS, which is defined as the time from the date of randomization to death from any cause); (c) Disease-free survival (DFS, which is the time from date of random assignment to date of recurrence or death).

Additional outcome(s): Secondary outcomes will include: (a) immune function evaluation; (b) quality of life (QoL) as evaluated by Karnofsky score and (c) treatment–related adverse effects assessment.

Data management: Two reviewers (Bin Han and Guangzong Sun) will be responsible for the data extraction independently according to the Cochrane Handbook for Systematic Reviews of Intervention. The following data will be extracted from eligible literatures: the first author, year of publication, country of study, participants (sample size, TNM stage, age, gender, inclusion and exclusion criteria, etc.), details of all experimental and control interventions regimen (manufacturer of the drugs, dosage of JLC, administration route, duration of treatment, follow-up time, etc.), outcomes (ORR, DCR, OS, DFS, QoL, immune function and adverse effects). For survival outcomes, Hazard ratios (HRs) with corresponding 95% confidence intervals (CIs) will be extracted from trials or be estimated from Kaplan–Meier survival curves by established methods. Any disagreements will be resolved by

discussion, and a third reviewer (Zhong Zheng) will make the final decision. Excluded studies and the reasons for exclusion will be listed in a table.

Quality assessment / Risk of bias analysis: The quality of the included RCTs will be assessed independently by 2 investigators (Jianwei Li and Bin Han) in terms of sequence generation, allocation concealment, blinding, incomplete outcome data, selective reporting and other bias, according to the guidance of the Cochrane Handbook for Systematic Review of Interventions. Evidence quality will be classified as low risk, high risk, or unclear risk of bias in accordance with the criteria of the risk of bias judgment. Any disagreements will be resolved via discussion with a third researcher (Guangzong Sun).

Strategy of data synthesis: Statistical analyses will be performed using Review Manager 5.3 (Nordic Cochran Centre, Copenhagen, Denmark) and Stata 14.0 (Stata Corp., College Station, TX, USA) statistical software. The outcomes were mainly represented by risk ratio (RR) with its 95% CIs. A two-tailed P value < 0.05 was considered statistically significant. Cochrane's Q-test and I2 statistics were used to assess heterogeneity between studies; P < 0.1 or I2 > 50% indicates statistical heterogeneity. A fixed effect model will be used to calculate the outcomes when statistical heterogeneity is absent; otherwise, the random effects model was considered according to the DerSimonian and Laird method.

Subgroup analysis: If the data are available and sufficient, subgroup and meta-regression analysis will be conducted to explore the source of heterogeneity with respect to age, gender, region, tumor stage, sample sizes, follow-up period, chemotherapy regimens and types of involved studies.

Sensibility analysis: Sensitivity analysis was conducted to explore an individual study's influence on the pooled results by deleting one single study each time from pooled analysis. A summary table will report the results of the sensitivity analyses.

Language: Language is limited with English and Chinese.

Country(ies) involved: China.

Keywords: Jinlong Capsule, gastric cancer, efficacy, meta–analysis, safety.

Dissemination plans: We will disseminate the results of this systematic review by publishing the manuscript in a peer-reviewed journal or presenting the findings at a relevant conference.

Contributions of each author:
Author 1 - Conceptualization; Investigation; Methodology; Project administration; Supervision; Writing-original draft; Writing-review & editing.
Author 2 - Investigation; Methodology; Writing-original draft; Writing-review & editing.
Author 3 - Investigation; Methodology; Writing-original draft.
Author 4 - Writing-original draft.
Author 5 - Methodology; Writing-review & editing.
Author 6 - Conceptualization; Methodology; Project administration; Supervision; Writing-review & editing.