INPLASY PROTOCOL

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Corresponding author:
Zhen Lin

2798968746@qq.com

Author Affiliation:
Department of Oncology, LongHua Hospital, Shanghai University of Traditional Chinese Medicine, Shanghai, China

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

Conflicts of interest:
All authors declare that they have no conflict of interest.

The clinical efficacy of traditional Chinese medicine in the treatment of malignant pleural effusion: A protocol of systematic review and meta-analysis

Lin, Z[1]; Jiang, M[2]; Gao, L[3]; Zhang, H[4].

Review question / Objective: **P: diagnosed as symptomatic malignant pleural effusion; I: traditional Chinese medicine; C: control groups were other treatment; O: clinical efficacy, QLQ-C30 questionnaire and safety; S: comparative design were included.**
Condition being studied: **Malignant pleural effusion.**
Information sources: **We will search Pubmed, Cochrane Central Register of Controlled Trials (CENTRAL), Web of Science, Embase as well as four Chinese databases, namely China National Knowledge Infrastructure (CNKI), Wanfang, Chinese Biomedical Literature Database (CBM) and Chinese Science and Technology Journal Database (VIP). All the English and Chinese literature published from inception to May 31, 2020 will be retrieved. In addition, we will also undertake a targeted gray literature search on ClinicalTrials.gov and the Chinese Clinical Trial Registry to gain unpublished or in-progress trials or completed but prepared for publication. Meanwhile, the reference list of previous clinical studies and reviews will be searched as supplementary sources.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 August 2020 and was last updated on 26 August 2020 (registration number INPLASY202080105).

INTRODUCTION

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METHODS

Participant or population: Patients diagnosed as symptomatic malignant pleural effusion.

Intervention: Traditional Chinese medicine.

Comparator: Other treatment.

Study designs to be included: comparative design.

Eligibility criteria: (1) aged 18-80 years; (2) definite pleural effusion with medium or above amount confirmed by X-ray or ultrasound; (3) advanced malignant tumor with MPE confirmed by histopathology or cytology; (4) the estimated survival time is more than 3 months; (5) Karnofsky score ≥ 60, ECOG PS score ≤ 2.

Information sources: We will search Pubmed, Cochrane Central Register of Controlled Trials (CENTRAL), Web of Science, Embase as well as four Chinese databases, namely China National Knowledge Infrastructure (CNKI), Wanfang, Chinese Biomedical Literature Database (C B M) a n d C h i n e s e S c i e n c e a n d Technology Journal Database (VIP). All the English and Chinese literature published from inception to May 31, 2020 will be retrieved. In addition, we will also undertake a targeted gray literature search on ClinicalTrials.gov and the Chinese Clinical Trial Registry to gain unpublished or in-progress trials or completed but prepared for publication. Meanwhile, the reference list of previous clinical studies and reviews will be searched as supplementary sources.

Main outcome(s): Clinical efficacy.

Additional outcome(s): QLQ-C30 questionnaire and safety.

Quality assessment / Risk of bias analysis: The following items will be independently assessed by two authors using the risk of bias assessment tool. (1) Was there adequate sequence generation (selection bias)? (2) Was allocation adequately concealed (selection bias)? (3) Was knowledge of the allocated interventions adequately prevented during the study? (4) Participants and personnel (performance bias) (5) Outcome assessors (detection bias) (6) Were incomplete outcome data adequately addressed (attrition bias)? (7) Are reports of the study free of suggestion of selective outcome reporting (reporting bias)? (8) Was the study apparently free of other problems that could put it at a risk of bias?

Strategy of data synthesis: Data will be pooled using the random-effects model but the fixed effect model will also be used to ensure robustness of the model chosen and susceptibility to outliers.

Subgroup analysis: Based on available data, we will perform the following subgroup analyses: different types of treatment.

Sensibility analysis: Excluding any very long or large studies to establish how much they dominate the results.

Country(ies) involved: China.

Keywords: protocol; systematic review; traditional Chinese medicine; malignant pleural effusion.

Contributions of each author:
Author 1 - Zhen Lin.
Author 2 - Mengyuan Jiang.
Author 3 - Lirong Gao.
Author 4 - Huachun Zhang.

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