INPLASY PROTOCOL

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Review Stage at time of this submission: Piloting of the study selection process.

Conflicts of interest: None.

Hyperthermic Intraperitoneal Chemotherapy combined with systemic chemotherapy for Gastric Cancer Peritoneal Carcinomatosis: a protocol for systematic review and meta analysis of randomised controlled trials

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Review question / Objective: Gastric cancer peritoneal carcinomatosis (GCPC) remains poor despite recent advances in systemic chemotherapy (SC) with an average survival less than six months. Current evidence supporting the utility of hyperthermic intraperitoneal chemotherapy (HIPEC) combined with SC for GCPC is limited. We plan to provide a systematic review and meta-analysis of randomised controlled trials to evaluate the comparative effects and safety of HIPEC combined with SC in the management of GCPC.

Condition being studied: Gastric Cancer Peritoneal Carcinomatosis (GCPC).

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 02 May 2020 and was last updated on 02 May 2020 (registration number INPLASY202050006).

INTRODUCTION

Review question / Objective: Gastric cancer peritoneal carcinomatosis (GCPC) remains poor despite recent advances in systemic chemotherapy (SC) with an average survival less than six months. Current evidence supporting the utility of hyperthermic intraperitoneal chemotherapy (HIPEC) combined with SC for GCPC is

limited. We plan to provide a systematic review and meta-analysis of randomised controlled trials to evaluate the comparative effects and safety of HIPEC combined with SC in the management of GCPC.

Rationale: We searched comparative studies evaluating HIPEC combined with SC vs. SC alone as the first-line treatment

for gastric cancer peritoneal carcinomatosis up to 31 March, 2020, using MEDLINE, EMBASE, the Cochrane Library, and Google Scholar.

Condition being studied: Gastric Cancer Peritoneal Carcinomatosis (GCPC).

METHODS

Search strategy: PubMed检索式: (((((((((Gastric Neoplasms) OR Stomach Neoplasm) OR Gastric Neoplasm) OR Cancer of Stomach) OR Stomach Cancers) OR Gastric Cancer) OR Gastric Cancers) OR Stomach Cancer) OR Cancer of the Stomach)) AND (((((((Hyperthermic Intraperitoneal Chemotherapy) OR Hyperthermic intra-operative peritoneal chemotherapy) OR Hyperthermic **Intraperitoneal Perfusion Chemotherapy)** OR HIPEC) OR intra-peritoneal hyperthermic perfusion) OR hyperthermic peritoneal perfusion) OR intraperitoneal hyperthermic chemotherapy) OR intraperitoneal hyperthermic chemoperfusion).

Participant or population: Patients who had been pathologically diagnosed as gastric adenocarcinoma / gastroesophageal junction adenocarcinoma with peritoneal metastasis will be included.

Intervention: Hyperthermic intraperitoneal chemotherapy combined with systemic chemotherapy.

Comparator: Systemic chemotherapy.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: HIPEC, including but not limited to: "intraperitoneal paclitaxel combined hyperthermia", "intraperitoneal hyperthermic perfusion", "hyperthermic peritoneal perfusion" and so on; excluding all studies of intraperitoneal chemotherapy or thermotherapy alone.

Information sources: MEDLINE, EMBASE, the Cochrane Library, and Google Scholar.

Main outcome(s): Median progression-free survival (mPFS).

Additional outcome(s): Median survival time (mOS), 1-year survival rate, 2-year survival rate, objective response rate (ORR), adverse events.

Data management: Two investigators independently extracted the appropriate data onto a standardized collection form. Any discrepancies were resolved by mutual discussion.

Quality assessment / Risk of bias analysis: Methodological quality of all studies was graded independently by the 2 investigators using The Cochrane Collaboration's tool for assessing risk of bias. The tool appraises the quality of study design with each of the item being assigned a judgment of high, low, or unclear risk.

Strategy of data synthesis: Risk ratios (RRs) were calculated for categorical variables. Hazard ratios (HRs) extrapolated from Kaplan- Meier curves were calculated for time-to-event outcomes. Weighted mean differences (WMDs) were calculated for continuous variables.

Subgroup analysis: Subgroup analyses will be performed based on chemotherapy regimens; gender; grade of cancer; anatomical position; combination mode of intraperitoneal chemotherapy and hyperthermia.

Sensibility analysis: The analysis model will be changed.

Language: English.

Country(ies) involved: China.

Keywords: Hyperthermic Intraperitoneal Chemotherapy; systemic chemotherapy; Gastric Cancer Peritoneal Carcinomatosis; meta-analysis; randomised controlled trials.

Dissemination plans: We will publish the review on completion.

Contributions of each author:

Author 1 - Yidan Lu - Author 1 drafted the manuscript.

Author 2 - Zheng Jin - The author provided statistical expertise.

Author 3 - Song Zheng - The author is the guarantor.

Author 4 - Yurong Bai - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.