INPLASY PROTOCOL

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

Conflicts of interest: **None.**

Efficacy of docetaxel combined carboplatin for the treatment of patients with castration-resistant prostate cancer: a protocol of systematic review and meta-analysis

Pu, CL[1]; Li, JZ[2]; Fan, LW[3].

Review question / Objective: **Is docetaxel combined carboplatin (DC) effective and safety for the treatment of castration-resistant prostate cancer (CRPC)?**
Condition being studied: **Castration-resistant prostate cancer, docetaxel, and carboplatin.**
Information sources: **This review will systematically and comprehensively retrieve all potential randomized controlled trials (RCTs) in MEDLINE, EMBASE, Cochrane Library, Web of Science, Cumulative Index to Nursing and Allied Health Literature, WANGFANG, Chinese Biomedical Literature Database, and China National Knowledge Infrastructure from the beginning up to the March 1, 2020, regardless the language and publication time limitations. All related RCTs that assessing the efficacy and safety of DC for the treatment of patients with CRPC will be considered for inclusion. We have created search strategy sample for MEDLINE, and will adapt similar search strategies for other electronic databases. In addition, we will also seek other resources for more potential studies, such as dissertations and reference lists of associated reviews.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 April 2020 and was last updated on 14 April 2020 (registration number INPLASY202040076).

INTRODUCTION

Review question / Objective: **Is docetaxel combined carboplatin (DC) effective and safety for the treatment of castration-resistant prostate cancer (CRPC)?**

Condition being studied: **Castration-resistant prostate cancer, docetaxel, and carboplatin.**

METHODS

Participant or population: We will include all male participants who were diagnosed as CRPC, in spite of their country, race, age, and duration and severity of CRPC.

Intervention: In the experimental group, all patients underwent DC as their treatment for CRPC.

Comparator: In the control group, there are no restrictions to the control treatments. However, we will exclude studies that utilized DC or any combination therapy with DC.

Study designs to be included: All potential randomized controlled trials (RCTs) that investigated efficacy and safety of DC for treatment of patients with CRPC will be included.

Eligibility criteria: All RCTs that investigated the efficacy and safety of DC compared with other treatments for patients with CRPC.

Information sources: This review will systematically and comprehensively retrieve all potential randomized controlled trials (RCTs) in MEDLINE, EMBASE, Cochrane Library, Web of Science, Cumulative Index to Nursing and Allied Health Literature, WANGFANG, Chinese Biomedical Literature Database, and China National Knowledge Infrastructure from the beginning up to the March 1, 2020, regardless the language and publication time limitations. All related RCTs that assessing the efficacy and safety of DC for the treatment of patients with CRPC will be considered for inclusion. We have created search strategy sample for MEDLINE, and will adapt similar search strategies for other electronic databases. In addition, we will also seek other resources for more potential studies, such as dissertations and reference lists of associated reviews.

Main outcome(s): Disease-free survival (defined as length of time after treatment during which no disease is found).

Additional outcome(s): Overall survival (defined as the time from randomization to death by any reasons); Progression-free survival (defined as the time from randomization to disease progression or death by any reasons); Prostate-specific antigen (PSA) response rate; Duration of PSA response; Quality of life (as measured by any relevant scales reported in the trials); and Adverse events.

Data management: Two team members will extract data using a pre-designed data extraction sheet. It comprises of the following information: publication information (such as first author, time of publication, et al), patient characteristics (such as race, age, eligibility criteria, duration and severity of CRPC), study design (sample size, randomization details, et al), details of treatment and comparators, outcome indicators, safety, follow-up data, and conflict of interest. Any differences between two members will be solved by consulting a third member and a consensus will be reached after discussion. If insufficient or missing data is examined, we will contact primary authors to request it.

Quality assessment / Risk of bias analysis: Two team members will independently assess methodological quality by Cochrane Collaboration's tool. We will appraise study quality for each eligible trial through seven aspects and each one is graded as low, unclear or high risk of bias. Any different views between two members will be settled by a third member through a consensus meeting.

Strategy of data synthesis: We will apply RevMan 5.3 software to analyze outcome data and a meta-analysis. If homogeneity is found, a fixed-effects model will be used for data pooling, and a meta-analysis will be carried out if sufficient data is extracted. On the other hand, if considerable heterogeneity is examined, a random-effects model will be utilized for data synthesis, and a subgroup analysis will performed to test the sources of remarkable heterogeneity. If we can still identify obvious heterogeneity, we will not

consider carrying out a meta-analysis. However, we will report this study results as a narrative summary.

Subgroup analysis: We will carry out a subgroup analysis to figure out sources of obvious heterogeneity across studies according to the different types of treatments, controls, and outcomes.

Sensibility analysis: We will conduct a sensitivity analysis to test the robustness of study findings by removing studies with high risk of bias.

Country(ies) involved: China.

Keywords: Castration-resistant prostate cancer; docetaxel; carboplatin; efficacy; safety.