INPLASY PROTOCOL

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

Conflicts of interest: **No.**

Can docetaxel combined prednisone effectively treat hormone refractory prostate cancer? a protocol of systematic review and meta-analysis

Cheng, L[1]; Yue, CF[2]; Wang, Y[3]; Cao, HF[4]; Dong, JF[5]; Dong, LX[6]; Chen, DY[7].

Review question / Objective: **Can docetaxel combined prednisone (DP) effectively treat hormone refractory prostate cancer (HRPC)?**
Condition being studied: **Hormone refractory prostate cancer; docetaxel; prednisone.**
Information sources: **The following electronic databases of Cochrane Library, PubMed, EMBASE, Web of Science, Cumulative Index to Nursing and Allied Health Literature, Chinese Biomedical Literature Database, and China National Knowledge Infrastructure will be examined to identify randomized controlled trials (RCTs) published from their inception to the March 1, 2020, regardless language and publication time limitations. All RCTs that test the efficacy and safety of DP for the treatment of patients with HRPC will be included in this study. The search strategy of Cochrane Library is presented. We will also adapt similar search strategies for other electronic databases. In addition, we will also check other literature sources, such as dissertations, conference proceedings, and reference lists of included trials.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 April 2020 and was last updated on 18 April 2020 (registration number INPLASY202040112).

INTRODUCTION

Review question / Objective: **Can docetaxel combined prednisone (DP) effectively treat hormone refractory prostate cancer (HRPC)?**

Condition being studied: **Hormone refractory prostate cancer; docetaxel; prednisone.**

METHODS

Participant or population: We will consider all male patients (aged 18 years or older) who were diagnosed as HRPC regardless their country, race, and severity of HRPC.

Intervention: Patients in the experimental group who received DP treatment alone will be included.

Comparator: Patients in the control group were allowed to receive all treatments, such radiotherapy, and surgery. However, we will exclude patients who also underwent any forms of DP.

Study designs to be included: We will include studies designed as all randomized controlled trials (RCTs) that specifically explore the efficacy and safety of DP for the treatment.

Eligibility criteria: We will include studies designed as all RCTs that specifically explore the efficacy and safety of DP for the treatment of patients with HRPC. We will exclude any other unqualified studies, such as laboratory studies, case report, case series, review, and non-clinical trials.

Information sources: The following electronic databases of Cochrane Library, PubMed, EMBASE, Web of Science, Cumulative Index to Nursing and Allied Health Literature, Chinese Biomedical Literature Database, and China National Knowledge Infrastructure will be examined to identify randomized controlled trials (RCTs) published from their inception to the March 1, 2020, regardless language and publication time limitations. All RCTs that test the efficacy and safety of DP for the treatment of patients with HRPC will be included in this study. The search strategy of Cochrane Library is presented. We will also adapt similar search strategies for other electronic databases. In addition, we will also check other literature sources, such as dissertations, conference proceedings, and reference lists of included trials.

Main outcome(s): Primary outcome is overall survival (defined as the time from randomization to death by any reasons). Secondary outcomes are 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, objective tumor response rate, disease-free survival (defined as length of time after treatment during which no disease is found), quality of life (as measured by any relevant scales reported in the trials), and adverse events.

Data management: Two investigators will independently extract data based on the pre-designed data extraction form. It includes study information (e.g. title, first author, and publication year), patient characteristics (e.g. age, race, sample size, eligibility criteria, and duration and severity of HRPC), trial setting, study design (e.g. details of randomization, allocation, and blind), interventions and controls (e.g. types of modalities, dosage, and session), outcomes, results, findings, and other relevant information. Any differences will be solved by a third investigator through discussion. Any missing data will be obtained from primary authors. If it is not available, we will only analyze data at hand using intention-to-treat analysis.

Quality assessment / Risk of bias analysis: Two investigators will independently appraise study quality of each eligible trial using Cochrane Collaboration's tool. Each trial will be assessed through seven aspects, and each item is rated as high, unclear or low risk of bias. Any discrepancies will be solved by a third investigator through consultation.

Strategy of data synthesis: RevMan 5.3 software will be employed for data synthesis and meta-analysis if possible. The pooled effects of continuous data will be expressed as mean difference or standardized mean difference and 95% confidence intervals (CIs). The pooled effects of dichotomous data will be exerted as risk ratio and 95% CIs. We will utilize I^2 test to estimate statistical heterogeneity. It

will be defined I^2 ≤50% as acceptable heterogeneity, and I^2 >50% as significant heterogeneity. We will a fixed-effect model to pool the outcome data if acceptable heterogeneity is examined, and meta-analysis will be performed if sufficient data is collected. We will carry out meta-analysis by pooling data relating to the primary and secondary outcomes where the interventions, populations and study contexts are sufficiently similar to make such analyses appropriate and interpretable. Otherwise, we will apply a random-effect model to synthesize the outcome data if considerable heterogeneity is found, and subgroup analysis will be carried out. If a meta-analysis can not be conducted, we will perform a narrative summary of study findings with supporting tables and figures, and will summarize narrative data reporting primary and secondary outcomes by describing the outcomes measured, methods of evaluation, and provide preliminary assessment of the efficacy data (e.g. overall survival, progression-free survival, PSA response rate, duration of PSA response, objective tumor response rate, and disease-free survival).

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: Hormone refractory prostate cancer; docetaxel; prednisone; efficacy; safety.