INPLASY PROTOCOL

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None declared.

The efficacy and safety of cabazitaxel in patients with metastatic castration-resistant prostate cancer: a system review and meta analysis of randomized controlled trials

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Review question / Objective: **In this meta-analysis, we aimed to assess the efficacy and safety of cabazitaxel of patients with metastatic castration-resistant prostate cancer(mCRPC).**
Condition being studied: **Cabazitaxel, as the new generation of taxane, has been approved for the treatment of patients with metastatic castration resistant prostate cancer who have previously received a regimen containing docetaxel. Compare with docetaxel, abazitaxel has roughly the same curative effect based on OS, PFS and radiographic tumor responses, also, has fewer complications in peripheral neuropathy, peripheral edema, alopecia, and nail disorders, in the meantime, cabazitaxel seems more easily accepted by patients. At present, there is no meta-analysis to evaluate the efficacy and safety of cabazitaxel in the treatment of mcrpc. The purpose of this systematic review is to conduct a meta analysis of cabazitaxel in the treatment of mCRPC to evaluate the efficacy and safety of this treatment regimen.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 October 2021 and was last updated on 07 October 2021 (registration number INPLASY2021100023).

INTRODUCTION

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METHODS

Participant or population: The patients were diagnosed with mCRPC.

Intervention: Cabazitaxel.

Comparator: Other treatments or placebo.

Study designs to be included: RCT.

Eligibility criteria: If all of the following criteria are met, it will be included in the study. (1) the patients were diagnosed with mCRPC. (2) Cabazitaxel was used as the experimental drug, and the control group was other drugs or placebo. (3) Case reports, systematic reviews, studies with insufficient data, non randomized controlled trials were excluded.(4) When multiple publication of the same study were available, the latest publication (including longer follow-up time and more events) was considered in the analysis.

Information sources: PubMed, Embase, Cochrane Central Register of Controlled Trials (CENTRAL), and ClinicalTrials.gov.

Main outcome(s): Median OS(overall survival).

Quality assessment / Risk of bias analysis: Two independent authors used Cochrane collaboration risk of bias Tool to assess the risk of bias, When there are divergence in quality evaluation, we introduce a third evaluator.

Strategy of data synthesis: We used Stata software (Stata16, download from https://www.stata.com/new-in-stata/) to process the collected data. For the classification results, we extracted the total number of people and the number of events, meanwhile, for continuous results, we extracted the number of samples, mean (SD or SE) or median according to the data provided in the paper. The intention-to-treat data set will be accepted when two or more set of results were provided. The pooled results of continuous results are presented as mean differences with 95% CI. Statistical result I2 was used to evaluate the heterogeneity between research results, in which heterogeneity is considered high about 75%,medium about 50%, low about 25%.To estimate the pooled treatment data, when chi-squared ($\chi 2$) <0.1 and heterogeneity coefficient (I2) $>50\%$, we used a random-effects model , otherwise, a fixed-effects model will be used. For all statistical results, $P < 0.05$ was considered statistically significant. Publication bias was not assessed because fewer than 10 studies were included.

Subgroup analysis: Decide whether to use subgroup analysis according to the actual situation.

Sensitivity analysis: Sensitivity analysis will be done by removing one study at a time and repeating the calculation.

Language: English.

Country(ies) involved: China.

Keywords: cabazitaxel; prostate cancer; efficacy; safety; meta-analysis; systematic review.

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