

# INPLASY PROTOCOL

To cite: Luo et al. Exploring the efficacy and pharmacological mechanisms of Chinese medicine in castration-resistant prostate cancer based on an integrated strategy of network pharmacology and Meta-analysis. Inplasy protocol 202250139. doi: 10.37766/inplasy2022.5.0139

Received: 23 May 2022

Published: 24 May 2022

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**Support:** Science office of sichuan.

**Review Stage at time of this submission:** Data analysis.

**Conflicts of interest:**  
None declared.

## Exploring the efficacy and pharmacological mechanisms of Chinese medicine in castration-resistant prostate cancer based on an integrated strategy of network pharmacology and Meta-analysis

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**Review question / Objective:** For patients with castration-resistant prostate cancer, does the combination of traditional Chinese medicine and modern medical treatment improve clinical symptoms and delay the progression of the disease compared with modern medical treatment alone?

**Condition being studied:** Prostate cancer (PCa) is one of the most common malignancies of the male urogenital system. Cancer statistics (2022) edition shows that the incidence of new prostate cancer accounts for 27% of the most common cancers diagnosed in men, the first place surpassing lung cancer and colorectal cancer, and the death it caused counts for 11% of all systemic malignancies in men. Patients who reach the CRPC stage have a poor prognosis with a median survival time of only 24-30 months. The role of TCM in tumor prevention and treatment is receiving increasing clinical attention. Previous studies have already confirmed the effectiveness of numerous TCM compounds and TCM components in treating PCa and demonstrated the advantages the TCM has, such as potentiation and improvement of patient quality of life, indicating great prospects for drug development in prohibiting the metastasis and progression of PCA.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 May 2022 and was last updated on 24 May 2022 (registration number INPLASY202250139).

### INTRODUCTION

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Chinese medicine and modern medical treatment improve clinical symptoms and delay the progression of the disease compared with modern medical treatment alone?

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## METHODS

**Participant or population:** Seven researchers participated in this study. A total of nine randomized controlled trials with 664 patients were included in this study. Two researchers independently evaluated the methodological quality of the literature using the Bias risk assessment tool in the Cochrane Manual [13]. Two researchers cross-checked the evaluation results and discussed the decision with a third researcher if necessary.

**Intervention:** Combination of TCM and modern medical treatment.

**Comparator:** The control group was not treated with Chinese herbal tonics, proprietary Chinese medicines, comfort therapy, or modern medicine alone.

**Study designs to be included:** The clinical trials included in this study are randomized controlled trials on the efficacy of combined TCM and modern medicine in treating CRPC, with no time or language restrictions. Self-reported controls, case

reports, and crossover studies were excluded from this study.

**Eligibility criteria:** Inclusion criteria of subjects Subjects were recruited following the criteria: (1) aged 18 years or above; (2) had a clear diagnosis of prostate cancer by pathological examination; meeting the diagnostic criteria of CRPC according to the Chinese Expert Consensus on the Diagnosis and Treatment of Destructive Resistance Prostate Cancer [8]; (3) excluded patients with primary malignancies other than combined prostate adenocarcinoma, and patients with severe heart, brain, liver, kidney, hematopoietic system diseases, and psychiatric patients; (4) had an expected survival of  $\geq 3$  months. Exclusion criteria (1) Trials that did not use the same baseline treatment (2) Trials with less than 15 subjects in any group (3) Treatment using acupuncture, or manipulation (4) Treatment using non-oral herbal medicine.

**Information sources:** We searched the databases of PubMed, EMBASE, Cochrane Library, Web of Science, China Biomedicine (CBM), China Wanfang database, China National Knowledge Infrastructure (CNKI), and VipInfo for clinical trials on the efficacy of TCM in treating CRPC without restrictions on the language or the year of publication.

**Main outcome(s):** The Concentration of serum prostate-specific antigen (PSA), disease progression, and clinical symptoms in Chinese medicine.

**Additional outcome(s):** (1) Quality of life: physical status, social and family status, emotional status, functional status, and other additional concerns; (2) Adverse effects.

**Quality assessment / Risk of bias analysis:** Two authors independently assessed the risk of bias following the guidelines in the Cochrane Handbook for the Systematic Evaluation of Interventions.

**Strategy of data synthesis:** Meta-analysis was performed using the Stata software

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(version 15.1). Continuous variables were described using standardized mean difference (SMD), and dichotomous variables were described using relative risk (RR) with the 95% confidential intervals (Cis). The included studies were first tested for their clinical heterogeneity, a fixed-effects model Meta-analysis was used for studies with no heterogeneity ( $P > 0.1$ ,  $I^2 < 50\%$ ), while a random-effects model was used for studies with heterogeneous results ( $P < 0.1$ ,  $I^2 > 50\%$ ).

**Subgroup analysis:** According to the treatment time: =3months; =6months.

**Sensitivity analysis:** Stata software performs sensitivity analysis. Reflect the sensitivity of this article by how the amount of effect changes after deleting an article.

**Country(ies) involved:** China.

**Keywords:** TCM and modern medicine; CRPC; RCT; meta-analysis.

**Contributions of each author:**

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