

# INPLASY PROTOCOL

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submission:** Preliminary searches.

## Conflicts of interest:

None declared.

## INTRODUCTION

**Review question / Objective:** Can the  
combination of Traditional Chinese  
Medicine for Fuzheng Buyi and western  
medicine achieve better efficacy and safety

## Effectiveness and Safety of Traditional Chinese Medicine for Fuzheng Buyi in the Treatment of Castration-Resistant Prostate Cancer: A Systematic Review and Meta-Analysis

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Li Q<sup>7</sup>.

**Review question / Objective:** Can the combination of  
Traditional Chinese Medicine for Fuzheng Buyi and western  
medicine achieve better efficacy and safety than similar  
western drugs in the treatment of castration-resistant  
prostate cancer? A systematic review and Meta-Analysis of  
randomized controlled trials.

**Eligibility criteria:** Inclusion criteria for diseases are strictly  
followed, including only castration-resistant prostate cancer,  
but not prostate cancer that has not developed into  
castration-resistant prostate cancer. Studies that involve the  
use of the Fuzheng Buyi Traditional Chinese Medicine and  
Western medicine combination therapy are included.  
Additionally, only studies with complete data records are  
included in this analysis.

**INPLASY registration number:** This protocol was registered with  
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of castration-resistant prostate cancer? A  
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randomized controlled trials.

**Condition being studied:** Prostate cancer is a prevalent malignancy of the male urinary tract, representing 27% of new malignant tumor cases in men worldwide and ranking first according to the Global Cancer Statistics Report 2022. In China, the incidence of prostate cancer is rapidly increasing, with an accompanying trend towards an earlier age of onset. Unfortunately, many patients with prostate cancer are diagnosed with advanced stages of the disease, including castration-resistant prostate cancer (CRPC), which has a poor prognosis and limited treatment options. While modern Western medicine has adopted endocrine therapeutic drugs, immunotherapeutic agents, and radiotherapy for the treatment of CRPC, they are not without limitations, including rapid resistance and adverse effects. Chinese medicine may offer a complementary approach, with a wider range of targets and fewer side effects. In this study, a meta-analysis was conducted to evaluate the efficacy and safety of Chinese herbal compound combined with Western medicine compared to conventional Western medicine in the treatment of CRPC. Additionally, the study can provide an evidence-based basis for clinical Chinese medicine treatment of CRPC.

## METHODS

**Participant or population:** Patients with a clear diagnosis of prostate cancer by pathological examination and meeting the two diagnostic criteria of CRPC: serum testosterone at depleted levels (<50 ng/dl or <1.7 nmol/l); three consecutive elevations of PSA after a one-week interval with a 50% or more increase in the low value.

**Intervention:** Chinese herbal formulas of the Fu Zheng and Bu Yi type or Chinese patent medicines combined with Western medical treatment methods, with the names of the Chinese herbal formulas containing "Fu Zheng", "Yi Qi", "BuYi", etc., or the formula is mainly based on Fu Zheng and Bu Yi.

**Comparator:** Western medical treatment methods, such as Chemotherapy and endocrine therapy.

**Study designs to be included:** Only trials that CRPC will be included.

**Eligibility criteria:** Inclusion criteria for diseases are strictly followed, including only castration-resistant prostate cancer, but not prostate cancer that has not developed into castration-resistant prostate cancer. Studies that involve the use of the Fuzheng Buyi Traditional Chinese Medicine and Western medicine combination therapy are included. Additionally, only studies with complete data records are included in this analysis.

**Information sources:** Such databases as CNKI, WanFang Data, VIP, CBM, PubMed, EMBase and Cochrane database were searched by the computer to search all the Randomized controlled trials about TCM prescriptions combined with Western drugs for castration-resistant prostate cancer.

**Main outcome(s):** ①Total effective rates;②TCM symptom scores;③FACT-P scores;④Adverse reaction;⑤PSA.

**Quality assessment / Risk of bias analysis:** A data extraction form will be developed based on the Cochrane handbook checklist of items to consider for data collection (section 7.3.a of the handbook). Two authors will independently extract the data from included studies. Disagreements will be resolved by discussion between the two reviewers and reviewing of the trial information. When needed the trial authors will be contacted for clarifications.

**Strategy of data synthesis:** The effect of continuous variables was evaluated using mean difference (MD), while the effect of dichotomous variables was evaluated using relative risk ratio (RR), and a 95% confidence interval (CI) was provided for both data. Statistical significance between the two groups was determined, and the  $\chi^2$  test combined with  $I^2$  was used to assess the level of heterogeneity among the

results of the studies. If  $P > 0.05$  and  $I^2 \leq 50\%$ , there was no statistical heterogeneity among the results, and a fixed-effects model was applied for the meta-analysis. If  $P \leq 0.1$  and  $I^2 > 50\%$ , it indicated significant heterogeneity among the studies, and subgroup analysis or sensitivity analysis was necessary to identify the source of heterogeneity. For this study, subgroup analysis was performed for the same outcome indicator with 10 or more included studies and heterogeneity present. For larger heterogeneity, sensitivity analysis was conducted using the one-by-one exclusion method, and the random-effects model was used for outcome analysis.

**Subgroup analysis:** When discussing the sources of heterogeneity in the article, it is necessary to consider the differences brought about by different types of interventions in conventional Western medicine, and the types of interventions can be discussed as subtypes.

**Sensitivity analysis:** Sensitivity analysis can not only evaluate the stability and reliability of meta-analysis merged results, but also evaluate whether the merged results have undergone significant changes due to the influence of individual studies. Sensitivity analysis is one of the most common statistical methods, which is mainly used to evaluate the robustness and reliability of the combined results of meta analysis. ① Using random effect model. ② After removing each included study one by one, merge the effects, change the inclusion exclusion criteria or remove a certain type of literature before merging the effects. ③ subgroup analysis. Examples include subgroup analysis of endocrine therapy and chemotherapy.

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

**Keywords:** Fuzheng-Buyi; CRPC; Meta-analysis.

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