INPLASY PROTOCOL

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

Conflicts of interest:
None.

Efficacy and safety of Bacillus Calmette-Guerin for bladder cancer: A protocol of systematic review

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Review question / Objective: **Is Bacillus Calmette-Guerin (BCG)effective and safe for patients with bladder cancer (BC)?**
Condition being studied: **Bacillus Calmette-Guerin; bladder cancer.**
Information sources: **The primary source of literatures will be searched from inception to present in MEDLINE, EMBASE, CINAHL, Science Direct, Cochrane Library, Web of Science, and China National Knowledge In¬frastructure. The secondary source of potential records will be identified from grey literatures, such as conference proceedings, thesis/ dissertations, and clinical trials registry. We build a preliminary search strategy of Cochrane Library (table 1). We will adapt similar search strategy for other electronic databases to avoid missing potential studies.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 11 July 2020 and was last updated on 11 July 2020 (registration number INPLASY202070042).

INTRODUCTION

Review question / Objective: **Is Bacillus Calmette-Guerin (BCG)effective and safe for patients with bladder cancer (BC)?**

Condition being studied: **Bacillus Calmette-Guerin; bladder cancer**

METHODS

Participant or population: **This study will include participants who were diagnosed as BC, in spite of their educational background, economic status, and stages of BC.**

Intervention: Patients who were treated with BCG for BC will be included.

Comparator: Patients who received other treatments will be selected as a comparator, except BCG.

Study designs to be included: This study only includes randomized controlled trials (RCTs) of BCG for patients with BC, regardless language and publication time.

Eligibility criteria: This study only includes RCTs of BCG for patients with BC, regardless language and publication time.

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Main outcome(s): Outcomes consist of pathological complete response, overall survival, progression-free survival, time to progression, recurrence-free survival, disease-free survival, and adverse events.

Data management: For all included studies, data will be extracted using a pilot tested data extraction form. It includes primary author, time of publication, trial setting, trial methods, country, trial population, age, eligibility criteria, treatments, controls, co-modalities, study limitations, study quality, outcomes, study findings, and other important data. Two authors will independently extract data from each eligible trial, and all divisions will be solved by a third author through discussion.

Quality assessment / Risk of bias analysis: Study quality of all included trials will be appraised using Cochrane risk of bias tool. This tool will evaluate 7 domains, and each one is rated as low, unclear or high risk of bias. We will clear up any confusion with the help of a third author through discussion.

Strategy of data synthesis: This study will employ RevMan 5.3 software to perform statistical analysis. All continuous outcome indicators will be expressed as weighted mean difference or standardized mean difference and 95% confidence intervals (CIs). All dichotomous outcome indicators will be showed as risk ratio and 95% CIs. We will quantify statistical heterogeneity using I^2 test. If $I^2 \leq 50\%$, we will pool outcome data using a fixed-effects model, and we will carry out meta-analysis if sufficient data on the same outcome is extracted. If $I^2 > 50\%$, we will synthesize outcome data using a random-effects model. In addition, we will perform a subgroup analysis to examine its possible heterogeneity sources.

Subgroup analysis: A subgroup analysis will be undertaken based on the differences in types of treatments, comparators, and study quality.

Sensibility analysis: A sensitivity analysis will be carried out to investigate the stability of study findings by taking away trials with low quality.

Country(ies) involved: China.

Keywords: Bladder cancer; Bacillus Calmette-Guerin; efficacy; safety.

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