INPLASY PROTOCOL

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

Conflicts of interest: **None.**

Efficacy of pirarubicin for non-muscle invasive bladder cancer: A protocol of systematic review and meta-analysis

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Review question / Objective: **Does pirarubicin effectively treat non-muscle invasive bladder cancer (NMIBC)?**
Condition being studied: **Non-muscle invasive bladder cancer; pirarubicin.**
Information sources: **A comprehensive literature search will be carried out in MEDLINE, EMBASE, Cochrane Library, Scopus, PsycINFO, Web of Science, Allied and Complementary Medicine Database, Chinese Biomedical Literature Database, and China National Knowledge Infrastructure from their initiation to the March 31, 2020. We will include any potential RCTs of pirarubicin for NMIBC regardless the language and publication time restrictions. We will create detailed search strategy for MEDLINE, and will modify similar search strategies for other electronic databases. We will also examine the websites of clinical trial registry for ongoing trials, dissertations, and reference lists of included studies.**

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 INPLASY202040113.

INTRODUCTION

Review question / Objective: **Does pirarubicin effectively treat non-muscle invasive bladder cancer (NMIBC)?**

Condition being studied: **Non-muscle invasive bladder cancer; pirarubicin.**

METHODS

Participant or population: **Patients who meet the diagnosis criteria of NMIBC will be included in this study, irrespective their age, race, sex, and duration of NMIBC.**

Intervention: **We will only include studies utilized pirarubicin as their interventional management.**

Comparator: **As for a comparator, it could be any treatments, such as surgery, radiotherapy. However, studies involved pirarubicin as their control treatment is not allowed.**

Study designs to be included: **All randomized controlled trials (RCTs)**

investigating the efficacy and safety of pirarubicin for NMIBC will be included.

Eligibility criteria: All RCTs investigating the efficacy and safety of pirarubicin for NMIBC will be included. We will exclude any other studies, except RCTs.

Information sources: A comprehensive literature search will be carried out in MEDLINE, EMBASE, Cochrane Library, Scopus, PsycINFO, Web of Science, Allied and Complementary Medicine Database, Chinese Biomedical Literature Database, and China National Knowledge Infrastructure from their initiation to the March 31, 2020. We will include any potential RCTs of pirarubicin for NMIBC regardless the language and publication time restrictions. We will create detailed search strategy for MEDLINE, and will modify similar search strategies for other electronic databases. We will also examine the websites of clinical trial registry for ongoing trials, dissertations, and reference lists of included studies.

Main outcome(s): Primary outcome Overall survival (defined as the length of time from randomization to death caused by any reasons), Progression-free survival (defined as the length of time from randomization to disease progression or death resulted from any causes). Secondary outcome Recurrence-free survival (defined as the length of time from randomization to the first time of either recurrence or relapse or death), Quality of life (as assessed by any scales reported in the trials), Rates of recurrence, and Adverse events.

Data management: Two researchers will independently perform data extraction using a previous created standardized data collection form. Any inconsistencies will be figured out with the help of another researcher, and a final decision will be reached after discussion. The extracted information comprises of publication information, author details, patient characteristics, study setting, trial design, sample size, details of intervention and controls, outcome indicators, safety data, follow-up information, results, findings, conflict of interests, and funding information. If we identify any insufficient or missing data, we will contact original authors to request them.

Quality assessment / Risk of bias analysis: The methodological quality of all included RCTs will be appraised by two independent researchers using Cochrane risk of bias tool. We will assess it on 7 criteria, and will grade each one as low, unclear or high risk of bias. Any uncertainty will be settled by another researcher through discussion.

Strategy of data synthesis: We will use RevMan 5.3 software to carry out statistical analysis. We will estimate treatment effects of continuous data as mean difference or standard mean difference and 95% confidence intervals (CIs), and dichotomous data as risk ratio and 95% CIs. Heterogeneity across included trials will be examined by I^2 statistic: $I^2 \leq 50\%$ exerts homogeneity, while $I^2 > 50\%$ suggests obvious heterogeneity. We will employ a fixed-effects model when homogeneity is found, and a meta-analysis will be conducted if possible. On the other hand, we will place a random-effects model if considerable heterogeneity is tested, and subgroup analysis will be performed to check the sources of such heterogeneity. If it is impossible to carry out a meta-analysis, we will undertake a narrative summary to address and report the merged outcome data instead.

Subgroup analysis: Subgroup analysis will be carried out to test the causes of significant heterogeneity in accordance with the differences in types of treatments, controls, and outcomes.

Sensibility analysis: Sensitivity analysis will be undertaken to test the robustness of merged results by omitting studies with high risk of bias.

Country(ies) involved: China.

Keywords: Non-muscle invasive bladder cancer; pirarubicin; efficacy; safety.