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 weekly amrubicin for refractory or relapsed non-small cell lung cancer: a protocol of systematic review and meta-analysis

Dang, D[1]; Jiang, C[2]; Xie, MR[3].

Review question / Objective: **Can weekly amrubicin (WA) effectively and safety treat refractory or relapsed non-small cell lung cancer (RRNSCLC)?**
Condition being studied: **Non-small cell lung cancer; amrubicin.**
Information sources: **We will perform literature searches using the following electronic bibliographic databases from their inception onwards to the March 31, 2020: Cochrane Library, MEDLINE, EMBASE, CINAHL, PsycINFO, Scopus, Chinese Biomedical Literature Database, WANGFANG, VIP database and China National Knowledge Infrastructure. We will not establish any limitations of language and publication status. The search strategy sample with detailed information of Cochrane Library is presented. In addition, similar search strategies will be adapted to the other electronic databases. At the same time, we will also search grey literature sources, such as conference abstracts, clinical trial registries, and reference lists of previous reviews.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 April 2020 and was last updated on 24 April 2020 (registration number INPLASY202040168).

INTRODUCTION

Review question / Objective: **Can weekly amrubicin (WA) effectively and safety treat refractory or relapsed non-small cell lung cancer (RRNSCLC)?**

Condition being studied: **Non-small cell lung cancer; amrubicin.**

METHODS

Participant or population: **All adult patients (over 18 years old) who were diagnosed as RRNSCLC regardless their gender, and educational and economic background will all be considered for inclusion.**

Intervention: All patients in the experimental group received WA for their treatment in this study.

Comparator: The participants in the control group could receive any therapies, except any types of WA.

Study designs to be included: This study will include randomized controlled trials (RCTs) of the efficacy and safety of WA for the treatment of RRNSCLC.

Eligibility criteria: In this study, we will only consider randomized controlled trials (RCTs) that focusing on the efficacy and safety of WA for the treatment of RRNSCLC for inclusion. Any other types of studies, such as animal studies, case reports, case series, and review will all be excluded.

Information sources: We will perform literature searches using the following electronic bibliographic databases from their inception onwards to the March 31, 2020: Cochrane Library, MEDLINE, EMBASE, CINAHL, PsycINFO, Scopus, Chinese Biomedical Literature Database, WANGFANG, VIP database and China National Knowledge Infrastructure. We will not establish any limitations of language and publication status. The search strategy sample with detailed information of Cochrane Library is presented. In addition, similar search strategies will be adapted to the other electronic databases. At the same time, we will also search grey literature sources, such as conference abstracts, clinical trial registries, and reference lists of previous reviews.

Main outcome(s): Primary outcomes are overall survival (defined as the time from randomization to death from any causes), and pathological complete response (defined as the complete disappearance of the invasive cancer in the lung and absence of tumor in the axillary lymph nodes). Secondary outcomes include progression-free survival, recurrence-free survival, disease-free survival, quality of life, and any expected or unexpected adverse events.

Data management: Two authors will independently extract the following associated information from each included trial: first author, time of publication, location, sample size, randomization methods, blinding, concealment, allocation, details of intervention and controls, number of sessions, duration of each session, duration of follow-up, outcome measurement tools, and any other relevant information. A third senior author will help to reconcile any divergences between two authors.

Quality assessment / Risk of bias analysis: Two authors will independently undertake quality assessment using Cochrane risk of bias tool, which assesses potential biases in the 7 domains. Each one is further determined as low, unclear or high risk of bias. A third senior author will reconcile any different views between two authors.

Strategy of data synthesis: We will undertake RevMan 5.3 software to analyze data and to perform meta-analysis if necessary. We will calculate all continuous data using mean difference or standardized mean difference and 95% confidence intervals. As for dichotomous data, we will exert it using risk ratio and 95% confidence intervals. All heterogeneity across included trials will be identified using I^2 statistics. $I^2 \leq 50\%$ indicates low heterogeneity, and a fixed-effect model will be utilized for data pooling. On the other hand, $I^2 > 50\%$ means high heterogeneity, and a random-effect model will be used for data synthesizing. Additionally, subgroup analysis will be operated to explore any possible reasons for the high heterogeneity. Whenever it possible, we will conduct meta-analysis if at least three fulfill the eligible criteria. Otherwise, meta-analysis will not be carried out if only one or two studies meet the inclusion criteria. Under such situation, the findings will be presented in a narrative summary. We will also perform narrative synthesis if running meta-analysis is inappropriate due to the high heterogeneity. All narrative descriptions will be carried out based on the Guidance on the Conduct of Narrative Synthesis in Systematic Reviews.

Subgroup analysis: We will preside over subgroup analysis to explore any potential heterogeneity and inconsistency based on the different characteristics of trial and patient, intervention and controls, and outcome measurement tools.

Sensibility analysis: We will consider running sensitivity analysis in order to identify the robustness and stability of merged results by excluding studies with high risk of bias.

Country(ies) involved: China.

Keywords: Non-small cell lung cancer; amrubicin; efficacy; safety.