INPLASY PROTOCOL

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Conflicts of interest:
The authors declare that there is no conflict of interest regarding the publication of this study.

Efficacy and safety of Aidi injection as an add-on therapy for advanced breast cancer: a systematic review and meta-analysis of randomized controlled trials

Yihui, C[1]; Yunzhi, C[2]; Wen, L[3]; Zhong, Q[4]; Jie, G[5]; Zhibin, J[6]; Yuhong, G[7]; Liancheng, G[8]; Mengzhi, Z[9]; Huaiquan, L[10]; Qingxue, W[11]; Changfu, Y[12].

Review question / Objective: **Whether should we use Aidi injection as an add-on therapy on advanced breast cancer.**
Condition being studied: **The review has not yet started, but we have already begin the preliminary searches. Twelve people were involved in the present study. Nine of them were trained well in performing a systematic review by Systematic Review Solutions or in Medical University of Western China. Our group have published two relevant systematic reviews before.**
Information sources: **Pubmed (https://www.ncbi.nlm.nih.gov/pubmed), Embase (http://www.embase.com), CNKI (http://www.cnki.net/), SinoMed (http://www.sinomed.ac.cn/) and the Cochrane Central Register of Controlled Trials(CENTRAL) (http://onlinelibrary.wiley.com/cochranelibrary/).**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 25 April 2020 and was last updated on 25 April 2020 (registration number INPLASY202040170).

INTRODUCTION

Review question / Objective: **Whether should we use Aidi injection as an add-on therapy on advanced breast cancer.**

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Western China. Our group have published two relevant systematic reviews before.

METHODS

Participant or population: Adult advanced breast cancer patients.

Intervention: Aidi injection plus conventional treatments.

Comparator: Conventional treatments.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: 1. Randomized controlled trial (Parallel groups or cross-over design). 2. Age>18 year. 3. Intervention with Aidi injection as an add-on therapy compared with conventional chemotherapy. 4. Reported ORR and adverse events or at least one additional outcome.

Information sources: Pubmed (https://www.ncbi.nlm.nih.gov/pubmed), Embase (http://www.embase.com), CNKI (http://www.cnki.net/), SinoMed (http://www.sinomed.ac.cn/) and the Cochrane Central Register of Controlled Trials (CENTRAL)(http://onlinelibrary.wiley.com/cochranelibrary/).

Main outcome(s): The primary outcome was overall response rate.

Additional outcome(s): Secondary outcomes included the QOL, immune cells and adverse events.

Quality assessment / Risk of bias analysis: Review Manager software (version 5.3; Cochrane Collaboration, Oxford, UK) will be used for estimating risks of bias of included studies.

Strategy of data synthesis: I2 and chi-square tests will be used to estimate heterogeneity. If P>0.1 or I2 <40%, the fixed effect model meta-analysis will be performed. When there is a high degree of heterogeneity, a random effect analysis will be used. For each group, Aidi injection group will be compared to placebo or other active chemotherapy. Weighted mean difference (WMD) or standard mean difference (SMD) will be used for analysis of continuous data and rate ratio (RR) will be calculated for dichotomous variable respectively.

Subgroup analysis: No subgroup analysis will be performed.

Sensibility analysis: The sensitivity analysis and publication bias test will performed using R language.

Language: No language limits will be imposed on the search.

Country(ies) involved: China.

Keywords: Aidi injection, Breast cancer, Cantharidin, Meta-analysis

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