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INPLASY

Clinical Effectiveness of Astragalus Injection in the Treatment of Viral Myocarditis in Children: A Systematic Review and Meta-Analysis

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ADMINISTRATIVE INFORMATION

Support - None.

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

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 December 2025 and was last updated on 24 December 2025.

INTRODUCTION

Review question / Objective This study aims to systematically evaluate the clinical effectiveness of Astragalus injection in the treatment of viral myocarditis in children by synthesizing evidence from randomized controlled trials.

Rationale

Regarding viral myocarditis, Hui(2023) conducted a meta-analysis evaluating the efficacy of oral Chinese medicine in adult patients. Subsequently, Zhang(2024) performed a meta-analysis across all age groups to assess the efficacy and safety of Shengmai san, while Jialiken(2025) reported a meta-analysis examining the therapeutic effects of intravenous Astragalus injection in adult patients. However, to the best of our knowledge, systematic reviews or meta-analyses evaluating the adjunctive effects of traditional Chinese medicine injections for viral myocarditis specifically in pediatric populations remain limited.

Therefore, this study aims to systematically evaluate the clinical efficacy of traditional Chinese medicine injections, particularly intravenous Astragalus injection widely used in clinical practice, for the treatment of pediatric viral myocarditis and to provide evidence to inform future treatment strategies.

Condition being studied

Pediatric viral myocarditis is a relatively common condition in children and adolescents, characterized by nonspecific inflammatory lesions of the myocardium induced by various viral infections, including adenovirus and Coxsackievirus B. The underlying patho-physiological mechanisms are believed to involve both direct viral-mediated myocardial injury and dysregulation of the host immune response; however, these mechanisms have not yet been fully elucidated. Although the prognosis is generally favorable in most pediatric patients, a

subset of cases may progress to a chronic course and eventually lead to heart failure.

Clinically, management primarily consists of supportive and conservative treatments, such as anti-infective or antiviral therapy, immunomodulation, and myocardial functional support, while established disease-specific therapies remain limited. In this context, the field of traditional medicine has continuously explored various interventions, including oral herbal formulations and herbal injections, to enhance therapeutic outcomes.

By systematically reviewing the existing literature and conducting a meta-analysis, the present study seeks to evaluate the evidence based clinical benefits of intravenous Astragalus injection in pediatric viral myocarditis, focusing on outcomes such as improvement of clinical symptoms, changes in myocardial enzyme levels, and recovery of electrocardiographic findings. Ultimately, this study aims to expand therapeutic options for pediatric patients with viral myocarditis.

METHODS

Search strategy

We will search electronically in English databases, Chinese databases, Korean databases, and a Japanese database. The search terms will include “viral myocarditis” and “Astragalus injection,” which will be adapted to the language and indexing specifications of each database.

Participant or population

[Inclusion Criteria]
Participants were children younger than 18 years.
Participants were clinically diagnosed with viral myocarditis according to recognized diagnostic criteria.

[Exclusion Criteria]
Participants had primary cardiomyopathy, severe viral myocarditis, or myocarditis or myocardial injury due to other etiologies.
Participants had severe arrhythmias, congenital heart disease, or other serious comorbid conditions, including major organ dysfunction.
Participants had concurrent infectious diseases or malignant tumors.
Studies in which additional pharmacological treatments, other than Astragalus injection combined with conventional Western medical treatment, were administered to the intervention group.
Studies in which changes or additions of medications that could affect the study outcomes were required during the treatment period.

Intervention

The experimental group received Astragalus injection administered intravenously in combination with conventional Western medical treatment.

Comparator

The control group received conventional Western medical treatment.

Study designs to be included

All the randomized controlled trials (RCTs) were included.

Eligibility criteria

All randomized controlled trials (RCTs) that investigated the clinical effectiveness of Astragalus injection combined with conventional Western medical treatment for viral myocarditis in children were included. Non-RCTs, RCT protocol, animal studies, case reports, thesis, survey and reviews were excluded.

Information sources

We will electronically search 11 following databases. Three English databases (MEDLINE via PubMed, EMBASE, the Cochrane Central Register of Controlled Trials), three Chinese databases(China National Knowledge Infrastructure, Wanfang database, and VIP), four Korean databases (such as Oriental Medicine Advanced Searching Integrated System, Korean studies Information Service System, Korea Citation Index, Research Information Sharing Service), and one Japanese databases(Citation Information by the National Institute of Informatics) without any language restrictions.

Main outcome(s)

1) Total effective rate
2) CK-MB levels

Additional outcome(s)

1) Other myocardial enzyme levels (e.g., CK, LDH, AST)
2) ECG recovery time
3) Adverse events

Quality assessment / Risk of bias analysis

Quality assessment will be performed using Risk of bias 2 (Rob2) tool from the Cochrane Handbook for Systematic Reviews of Interventions. The tool includes bias arising from the randomization process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in the measurement of the outcome, and bias in the selection of reported results.

Strategy of data synthesis
Data will be synthesized using Review Manager 5.4 software. Dichotomous outcomes will be summarized using risk ratios (RRs) with 95% Confidence Intervals (CIs). Continuous outcomes will be presented as the standard mean difference (SMD) or mean difference (MD) with 95% CIs. Heterogeneity will be evaluated using the Higgins I2 index, with I2 ≥ 50% indicating potential heterogeneity, and I2 ≥ 75% indicating considerable heterogeneity.

Subgroup analysis
If considerable heterogeneity (I2 ≥ 75%) is detected, subgroup analyses will be conducted based on treatment duration, according to the duration of Astragalus injection reported in the included studies. Subgroup analyses will be performed where sufficient data are available.

Sensitivity analysis
Sensitivity analysis will be performed by excluding one study at a time to assess the robustness of the meta-analysis results.

Language restriction No language restriction.

Country(ies) involved Republic of Korea.

Keywords
children; viral myocarditis; Astragalus injection; traditional Chinese medicine; Systematic review; Meta-analysis.

Dissemination plans
children; viral myocarditis; Astragalus injection; traditional Chinese medicine; Systematic review; Meta-analysis.

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