

## Shenkang Injection for the Treatment of Acute Kidney Injury: A Systematic Review and Meta-Analysis

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Liao, SC<sup>1</sup>; Chen, YR<sup>2</sup>; Wang, ST<sup>3</sup>; Ye, CY<sup>4</sup>.

### Corresponding author:

Shengchun Liao

shengchunliao888@outlook.com

### Author Affiliation:

Department of Nephrology,  
Shuguang Hospital Affiliated to  
Shanghai University of Traditional  
Chinese Medicine.

### ADMINISTRATIVE INFORMATION

**Support** - National Science Foundation of China (82170747).

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

**Conflicts of interest** - None declared.

**INPLASY registration number:** INPLASY2023100037

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 October 2023 and was last updated on 08 October 2023.

### INTRODUCTION

**Review question / Objective** Shenkang Injection for the Treatment of Acute Kidney Injury: A Systematic Review and Meta-Analysis.

**Condition being studied** Acute kidney injury (AKI) is a prevalent clinical condition characterized by a high mortality rate. Unfortunately, there are currently no effective treatments available to promote renal recovery in AKI. Previous studies have indicated that various Chinese herbal medicines can protect the kidneys in cases of AKI through different mechanisms of action. ShenKang injection (SKI), an injectable preparation containing four Chinese herbal extracts, has shown potential effectiveness in treating AKI in several clinical trials. The aim of this meta-analysis is to systematically evaluate the efficacy of SKI in the treatment of AKI.

### METHODS

**Participant or population** Patients with acute kidney injury used without shenkang injection or used placebo.

**Intervention** A randomized controlled trial comparing the use of SKI with no SKI for the treatment of AKI. The exclusion criteria were as following:(1) Trials that did not meet the inclusion criteria. (2) Studies that used oral or rehydration forms of herbal preparations other than SKI. (3) Participants with other types of renal disease, congenital renal anomalies, and individuals who underwent renal surgeries. (4) Systematic reviews, conference papers, and animal experiments. (5) Duplicate publications.

**Comparator** A randomized controlled trial comparing the use of SKI with no SKI for the treatment of AKI. The exclusion criteria were as following:(1) Trials that did not meet the inclusion

criteria. (2) Studies that used oral or rehydration forms of herbal preparations other than SKI. (3) Participants with other types of renal disease, congenital renal anomalies, and individuals who underwent renal surgeries. (4) Systematic reviews, conference papers, and animal experiments. (5) Duplicate publications.

**Study designs to be included** Randomized controlled trial.

**Eligibility criteria** The inclusion criteria for this study consisted of a randomized controlled trial comparing the use of SKI with no SKI for the treatment of AKI. There were no restrictions on patient characteristics, such as gender, age, religion, language, or country of origin. The diagnosis of AKI was based on the criteria established by the Acute Kidney Injury Network (AKIN) in 2005[14], which includes an increase in creatinine levels by 1.5 to 2.0 times the baseline level or a creatinine increase of at least 26.4  $\mu\text{mol/L}$ . These criteria also include a urine output of less than 0.5 ml/kg/hr for at least 6 hours within the past 48 hours. Alternatively, the criteria established by the Kidney Disease: Improving Global Outcomes (KDIGO) in 2012[2] were used, which include an increase in serum creatinine (SCr) levels by  $\geq 0.3$  mg/dl ( $\geq 26.5$   $\mu\text{mol/l}$ ) within 48 hours, an increase in SCr to  $\geq 1.5$  times the baseline level presumed to have occurred within the prior 7 days, or a urine volume of  $< 0.5$  ml/kg/h for 6 hours. In the control group, interventions included the use of conventional pharmacotherapy, as well as hormones, immunosuppressants, and renal replacement therapy. There were no restrictions on the dose, type, frequency, or duration of SKI treatment. Placebo trials were also included. The intervention in the experimental group consisted of a combination of SKI therapy and the interventions used in the control group. The following studies were excluded for the following reasons: (1) Trials that did not meet the inclusion criteria. (2) Studies that used oral or rehydration forms of herbal preparations other than SKI. (3) Participants with other types of renal disease, congenital renal anomalies, and individuals who underwent renal surgeries. (4) Systematic reviews, conference papers, and animal experiments. (5) Duplicate publications.

**Information sources** Using the seven databases of PubMed, Embase, Cochrane Library, CNKI, WanFang Data, CBM, and VIP Database. A systematic literature search was conducted in October 8th, 2023. The language was restricted to English and Chinese.

**Main outcome(s)** Serum Creatinine: no serum or urine biomarkers have been found to be more reliable than SCr in indicating AKI. Therefore, the SCr definition of AKI remains the best choice for clinical research.

#### **Quality assessment / Risk of bias analysis**

According to the "Risk of bias" evaluation tool in the Cochrane Handbook for Systematic Reviews, two authors independently assessed the risk of bias in the included studies. The risk assessment consisted of seven items: (1) random sequence generation, (2) allocation concealment, (3) blinding of participants and personnel, (4) blinding of outcome assessment, (5) incomplete outcome data, (6) selective reporting, and (7) other bias. These items were evaluated as having a "high risk of bias", "low risk of bias" or "unclear risk of bias" based on the assessment criteria.

#### **Strategy of data synthesis**

The primary focus of this study was the measurement of serum creatinine (SCr), with secondary measurements including blood urea nitrogen (Bun), cystatin C (CysC), 24-hour urine protein (24h-Upro), and APACHII scores. Two authors conducted independent data extraction using a predetermined search strategy. Initially, a preliminary screening was performed based on the titles and abstracts of the search results to exclude studies that clearly did not meet the criteria. Subsequently, a full-text reading assessment was conducted to determine whether the inclusion criteria were met. The two authors compared the selected studies, resolving any disagreements through discussion or with the assistance of a third author. The data were then categorized by the following: author's name, year of publication, subject information, intervention, duration, outcome, and adverse events. These data were compiled into spreadsheets.

**Subgroup analysis** This meta-analysis will create serum creatinine subgroup by age, treatment duration, hemodialysis and immunosuppressant.

**Sensitivity analysis** Sensitivity analysis of serum creatinine, blood urea nitrogen, cystatin c, 24-hour urine protein and APACHE II score will be created.

**Country(ies) involved** China.

**Keywords** Acute Kidney Injury; shenkang injection; meta-analysis; systematic review; traditional Chinese medicine.

#### **Contributions of each author**

Author 1 - Shengchun Liao - Initiated the study and participated in its design, responsible for study

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selection, data extraction, and data analysis and drafted the manuscript.

Email: shengchunliao888@outlook.com

Author 2 - Yurou Chen - Drafted the manuscript.

Email: 714331974@qq.com

Author 3 - Shuting Wang - Responsible for study selection, data extraction, and data analysis.

Email: wst586800@163.com

Author 4 - Chaoyang Ye - Initiated the study and participated in its design, oversaw all aspects of the study.

Email: yechaoyang63@126.com