

# INPLASY PROTOCOL

## Effects and safety of Wuling Powder versus western medicine in the Treatment of hyperuricemia: A Meta-Analysis of clinical trials

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

**Conflicts of interest:**  
No conflict of interest.

**Review question / Objective:** Does Wulingsan or its modified prescription work better than conventional medical therapies? **Condition being studied:** Hyperuricemia (HUE) occurs when the concentration of serum uric acid (SUA), determined by the production and excretion of urate, exceeds a normal standard. HUE has drawn increasing attention in recent decade because of its increasing prevalence in the China. 3 hypouricemic drugs are commonly used for the treatment (i.e. probenecid, benzbromarone and allopurinol). Although these treatments have very good results as hypouricemic agents, they may be associated with gastrointestinal reactions, liver and kidney damage, and other adverse effects. Therefore, it is imperative to explore new available approaches for gouty arthritis, especially complementary and alternative medicine. Wulingsan (WLS) is a Chinese herbal formula widely used in clinical practice. Previous laboratory and clinical studies have shown WLS and its modification may work in lowering SUA. However, these results are far from being conclusive due to the limited power and potential sampling errors as a result of their small sample sizes. As such, in this study, we therefore designed this meta-analysis to investigate the efficacy and safety of WLS and its modification in the treatment of HUE.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 April 2020 and was last updated on 16 April 2020 (registration number INPLASY202040097).

### INTRODUCTION

**Review question / Objective:** Does Wulingsan or its modified prescription work better than conventional medical therapies?

**Condition being studied:** Hyperuricemia (HUE) occurs when the concentration of serum uric acid (SUA), determined by the production and excretion of urate, exceeds

a normal standard. HUE has drawn increasing attention in recent decade because of its increasing prevalence in the China. 3 hypouricemic drugs are commonly used for the treatment (i.e. probenecid, benzbromarone and allopurinol). Although these treatments have very good results as hypouricemic agents, they may be associated with gastrointestinal reactions, liver and kidney damage, and other adverse effects. Therefore, it is imperative to

explore new available approaches for gouty arthritis, especially complementary and alternative medicine. Wulingsan (WLS) is a Chinese herbal formula widely used in clinical practice. Previous laboratory and clinical studies have shown WLS and its modification may work in lowering SUA. However, these results are far from being conclusive due to the limited power and potential sampling errors as a result of their small sample sizes. As such, in this study, we therefore designed this meta-analysis to investigate the efficacy and safety of WLS and its modification in the treatment of HUE.

## METHODS

**Participant or population:** Patients diagnosed as hyperuricemia.

**Intervention:** Wulingsan or modified Wulingsan without combining other modern medicine (except the modern medicine is equally administered in both groups).

**Comparator:** Allopurinol, Benzbromarone and/or Febuxostat, with or without combining other modern medicine.

**Study designs to be included:** Random controlled trial.

**Eligibility criteria:** Any study meets with the requirement of PICO and study design listed in item 12, 13,14, 15 and 18. Besides, studies need to be reported in English or Chinese. Only 1 of repeated publications based on 1 same set of data will included. Studies with data that cannot be extracted will not be included. Studies that made inarguable mistakes will not be included.

**Information sources:** CNKI、wanfang data、VIP Database for Chinese Technical Periodicals、PubMed、Embase、Cochrane library.

**Main outcome(s):** Main outcome is the end-point serum uric acid. The specific measures include serum uric acid level and/or overall response rate in lowering

SUA (Only performed when such data is available, and the overall response rate in solving the general symptoms of gout shall be excluded).

**Quality assessment / Risk of bias analysis:** Cochrane GRADE; Jadad Rating scale.

**Strategy of data synthesis:** Continuous data (SUA level) were measured by standardized mean difference (SMD) and 95% confidence interval (CI) were calculated. Enumeration data (overall efficacy and adverse reactions) were evaluated by relative risk (RR) and 95% CI. Statistical heterogeneity was assessed using a Chi-square test or by calculating Higgins  $I^2$  values. The proper effect models were chosen in accordance with the results: when  $I^2$  is less than 50%, fixed effects models were chosen, and when  $I^2$  is more than 50%, a random effects model was applied. Subgroup and analysis was used to explore the source of heterogeneity. The Cochrane Collaboration Review Manager Software was used for all statistical analyses, and all  $p$  values were two sided.

**Subgroup analysis:** Whether and how Wulingsan was modified in the study; Different treatment courses; Different literature quality (if the GRADE or jaded shows highly dispersed study quality).

**Sensibility analysis:** Performed when there persists heterogeneity that cannot be accounted for by subgroup analysis.

**Country(ies) involved:** China.

**Keywords:** Hyperuricemia, Wuling Powder, Meta analysis.