INPLASY

Efficacy of Spleen-Invigorating Compound Formulas on Short Stature in Children: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Preliminary searches.

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 14 June 2026 and was last updated on 14 June 2026.

INTRODUCTION

Review question / Objective Objective: To compare the efficacy/safety of spleen-strengthening traditional Chinese medicine in the treatment of short stature in children.
P: children with short stature.
I: Oral Administration of Spleen-Strengthening Compound Traditional Chinese Medicine.
C: Conventional drugs or placebo.
O: Height, height velocity ,height SDS, bone age, IGF-1, IGFBP-3.
S: RCTs.

Condition being studied Short Stature (SS) signifies a condition characterized by a height value ≥2 standard deviation scores (SDS) below the mean for age, sex, and ethnicity—equivalent to below the 3rd percentile. Height serves as a critical biomarker reflecting health status, nutrition, and developmental progress in children and adolescents. One of the most common pediatric complaints, pediatric short stature garners significant attention from families and public health systems. Societal emphasis on ideal stature coupled with widespread "height anxiety" among parents has led to an escalated public focus. Consequently, pediatric endocrinology consultations related to height concerns demonstrate a sharp upward trend—reflecting substantial social demand and a mounting burden on healthcare infrastructures globally.

The etiology of short stature encompasses complex regulation by multi-faceted factors. Current Western medical approaches primarily employ recombinant growth hormone (rGH); limitations such as patient compliance challenges, economic barriers, and potential adverse effects undermine its broader clinical applicability. Traditional Chinese Medicine (TCM) utilizes spleen-strengthening herbal compounds to enhance growth velocity while delaying bone age progression. This meta-analysis systematically evaluates clinical efficacy and safety profiles of spleen-based TCM interventions in children with short stature, thereby providing evidence-based guidance for clinical practice.

METHODS

Participant or population The systematic review and meta-analysis will include children diagnosed with short stature (SS). Participants will comprise children of any gender, age range (based on the pediatric cohort under investigation), and ethnicity.

Intervention Oral Traditional Chinese Medicine interventions focusing on spleen-strengthening herbal compounds for short stature will involve the following regimens:
Monomedication Group: Solely administered spleen-strengthening Chinese herbal formulas.
Combined Therapy Group: Spleen-strengthening Chinese herbal formulas integrated with conventional growth hormone (GH) therapy.

Comparator Conventional drugs or placebo: growth hormone(GH).

Study designs to be included Only randomized controlled trials(RCTs) will be inlcuded in this study.

Eligibility criteria Additional Inclusion Criteria:
Intervention: Treatment groups must exclusively employ spleen-strengthening TCM herbal compounds as either:
Monomedication: Sole traditional Chinese herbal formulas; Combined Therapy: With concurrent growth hormone (GH).
Control: Control groups must use growth hormone (GH) or placebo (no alternative therapy).
Outcomes: Studies must report ≥1 of the following predefined outcomes at endpoint:
Height Parameters: Height, Height SDS (standard deviation score); Biological Markers: IGF-1, IGFBP-3; Skeletal Age: Bone Age assessment; Safety Metrics: Adverse event rates.
Duration: Minimum intervention must be ≥12 weeks.
Additional Exclusion Criteria:
Non-conforming TCM:Interventions not prioritizing spleen-strengthening as primary mechanism.
Data Quality: Lack of critical meta-analysis data (SDs; baseline characteristics; outcome metrics).
Inadequate Timing: Drug intervention duration <12 weeks.
Evidence Tier: Dissertations, reports, conference abstracts, non-peer-reviewed work.

Information sources Wanfang Data、VIP Information、CNKI、Chinese Biomedical Literature Database、PubMed、Embase、Cochrane library、Web of Science..

Main outcome(s) Height, height velocity ,height SDS(HtSDS).

Additional outcome(s) bone age, IGF-1, IGFBP-3.

Quality assessment / Risk of bias analysis The methodological quality of the included randomized controlled trials (RCTs) was assessed using the Cochrane Risk of Bias 2 (RoB 2) tool. Two reviewers will independently evaluate each study. Disagreements will be resolved through discussion, or by consultation with a third reviewer when necessary.

Strategy of data synthesis Data will be synthesized using Review Manager (RevMan) 5.4.1 software. Dichotomous outcomes will be summarized using Risk Ratios (RRs) with 95% Confidence Intervals (CIs). Continuous outcomes will be presented as Mean Difference (MD) or Standardized Mean Difference (SMD) with 95% CIs. Heterogeneity will be quantified using the Higgins I^2 index, with $I^2 > 50\%$ indicating substantial heterogeneity and $I^2 > 75\%$ indicating considerable heterogeneity.

Subgroup analysis If sufficient data are available, subgroup analyses will be conducted according to the type of Spleen-Strengthening Compound Traditional Chinese Medicine, such as simple use of Spleen-Strengthening Compound Traditional Chinese Medicine, combination with other Traditional Chinese Medicine, or different formulations (e.g., decoction, granule, pill). Additional subgroup analyses may be considered according to comparator type (e.g., placebo, western medicine such as growth hormone), treatment duration, outcome measurement scale (e.g., variations in height measurement methods or evaluation criteria), provided relevant data are available. Subgroup findings will be interpreted cautiously owing to an expected small number of studies and potential clinical heterogeneity.

Sensitivity analysis Sensitivity analyses, conducted where sufficient studies are available, will assess the robustness of pooled results in this meta-analysis. Analyses may encompass:
1. Excluding studies judged to be at high risk of bias based on predefined methodological standards (e.g., inadequate randomization or blinding in RCT design).
2. Excluding studies with incomplete or imputed data (e.g., missing standard deviations or unverified growth parameter outcomes).
3. Comparing results using distinct statistical models.

Results from sensitivity analyses will guide interpretation and strengthen the validity of final pooled estimates, particularly for clinical outcomes related to growth efficacy in pediatric patients.

Country(ies) involved China.

Keywords Traditional Chinese Medicine (TCM); short stature (SS); spleen-strengthening; randomized controlled trial (RCT); meta-analysis; clinical efficacy.

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