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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Data analysis.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202650105

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 May 2026 and was last updated on 18 May 2026.

INTRODUCTION

Review question / Objective To evaluate the clinical efficacy and safety of Shuxuening Injection (SXNI) in the treatment of acute ischemic stroke.

Condition being studied Shuxuening Injection (SXNI), a Chinese herbal injectable preparation derived from Ginkgo biloba leaves, is widely used as an adjunctive therapy for ischemic cerebrovascular disease.

METHODS

Search strategy

1. CNKI: (主题=舒血宁注射液 OR 主题=舒血宁 OR 主题=银杏叶提取物) AND (主题=急性缺血性卒中 OR 主题=急性脑梗死 OR 主题=缺血性脑卒中 OR 主题=脑梗死) AND (主题=随机对照试验 OR 主题=随机)

2. Wanfang

主题:(舒血宁注射液 OR 舒血宁 OR 银杏叶提取物) AND 主题:(急性缺血性卒中 OR 急性脑梗死 OR 缺血性脑卒中 OR 脑梗死) AND 主题:(随机对照试验 OR 随机 OR RCT)

3. VIP

M=(舒血宁注射液 OR 舒血宁 OR 银杏叶提取物) AND M=(急性缺血性卒中 OR 急性脑梗死 OR 缺血性脑卒中 OR 脑梗死) AND M=(随机对照试验 OR 随机 OR RCT)

4. PubMed:

#1 "Shuxuening Injection"[Title/Abstract] OR "Shuxuening"[Title/Abstract] OR "Ginkgo biloba extract"[Title/Abstract] OR "Ginkgo biloba"[Title/Abstract] OR "ginkgo leaf extract"[Title/Abstract] OR "ginkgo diterpene lactones"[Title/Abstract] OR "ginkgo flavonoids"[Title/Abstract]
#2 "Acute Ischemic Stroke"[Title/Abstract] OR "Acute Ischaemic Stroke"[Title/Abstract] OR "Acute Cerebral Infarction"[Title/Abstract] OR "Ischemic Stroke"[Title/Abstract] OR "Ischaemic Stroke"[Title/Abstract] OR "Cerebral

Infarction"[Title/Abstract] OR "Brain Ischemia"[Title/Abstract] OR "Cerebral Ischemia"[Title/Abstract] OR "Acute Stroke"[Title/Abstract]
 #3 "Randomized Controlled Trial"[Publication Type] OR "Randomized Controlled Trial"[Title/Abstract] OR "Randomized"[Title/Abstract] OR "Randomised"[Title/Abstract] OR "RCT"[Title/Abstract] OR "Controlled Clinical Trial"[Publication Type] OR "Clinical Trial"[Title/Abstract]
 #4 #1 AND #2 AND #3

5.EmBase:

#1. (Shuxuening Injection or Shuxuening or Ginkgo biloba extract or Ginkgo biloba).ti,ab.
 #2. exp *Ginkgo biloba extract/
 #3. #1 or #2
 #4. (acute ischemic stroke or acute ischaemic stroke or acute cerebral infarction or ischemic stroke or ischaemic stroke or cerebral infarction).ti,ab.
 #5. exp *ischemic stroke/
 #6. #4 or #5
 #7. (randomized controlled trial or randomized or randomised or RCT or controlled clinical trial).ti,ab.
 #8. exp *randomized controlled trial/
 #9. #7 or #8
 #10. #3 and #6 and #9
 #11. limit #10 to (human and embase)

6.Cochrane Library:

#1 MeSH descriptor: [Ginkgo biloba] explode all trees
 #2 (Shuxuening Injection or Shuxuening or Ginkgo biloba extract):ti,ab,kw
 #3 #1 or #2
 #4 MeSH descriptor: [Ischemic Stroke] explode all trees
 #5 MeSH descriptor: [Brain Ischemia] explode all trees
 #6 (acute ischemic stroke or acute ischaemic stroke or acute cerebral infarction or ischemic stroke or cerebral infarction):ti,ab,kw
 #7 #4 or #5 or #6
 #8 (randomized controlled trial or randomized or randomised or RCT):ti,ab,kw
 #9 #3 and #7 and #8

7.Clinicaltrials.gov:

Condition: Acute Ischemic Stroke OR Ischemic Stroke OR Cerebral Infarction
 Intervention: Shuxuening Injection OR Ginkgo biloba extract OR Ginkgo biloba
 Study Type: Interventional Studies (Clinical Trials)
 Status: Completed (but not yet published).

Participant or population Those with a definite diagnosis of AIS according to the Chinese

Guidelines for Diagnosis and Treatment of Acute Ischemic Stroke or the International Classification of Diseases (ICD) criteria, with no restrictions on sex, age, or race, and all patients were required to be in the acute phase (within 7 days of onset).

Intervention The intervention group received SXNI in addition to conventional treatment, with no dose restrictions and a minimum treatment duration of 2 weeks.

Comparator The control group received CT alone or CT plus placebo.

Study designs to be included RCTs.

Eligibility criteria The inclusion criteria were as follows: (1) Patients: those with a definite diagnosis of AIS according to the Chinese Guidelines for Diagnosis and Treatment of Acute Ischemic Stroke or the International Classification of Diseases (ICD) criteria, with no restrictions on sex, age, or race, and all patients were required to be in the acute phase (within 7 days of onset). (2) Intervention: the intervention group received SXNI in addition to conventional treatment, with no dose restrictions and a minimum treatment duration of 2 weeks. (3) Comparison: the control group received CT alone or CT plus placebo. (4) The primary outcome measure was the overall clinical response rate (defined according to the scoring criteria for neurological deficits in stroke, including terms such as effective, markedly effective, and cured). Secondary outcome measures included neurological deficit score (NIHSS), ADL (Barthel Index), lipid profile parameters (total cholesterol [TC], triglycerides [TG], low-density lipoprotein [LDL], high-density lipoprotein [HDL]), and the incidence of adverse reactions. (5) Study design: RCTs, regardless of blinding or allocation concealment, with no language restrictions.

Information sources CNKI, Wanfang Data, VIP, PubMed, EmBase, and the Cochrane Library.

Main outcome(s) Overall clinical response rate (defined according to the scoring criteria for neurological deficits in stroke, including terms such as effective, markedly effective, and cured).

Additional outcome(s) Neurological deficit score (NIHSS), ADL (Barthel Index), lipid profile parameters (total cholesterol [TC], triglycerides [TG], low-density lipoprotein [LDL], high-density lipoprotein [HDL]), and the incidence of adverse reactions.

Quality assessment / Risk of bias analysis

Cochrane Collaboration's Risk of Bias tool.

Strategy of data synthesis A random-effects model was used for all analyses to account for potential variability among studies.

Subgroup analysis Subgroup analyses were conducted based on publication year, sample size, age, sex, time from onset to treatment, dosage of SXNI, and treatment duration.

Sensitivity analysis Sensitivity analysis was performed by sequentially excluding each individual study to assess the robustness of the pooled results.

Language restriction No restriction.

Country(ies) involved China.

Keywords Shuxuening injection; acute ischemic stroke; therapeutic effects; systematic review; meta-analysis.

Contributions of each author

Author 1 - Gonggang Gao.

Author 2 - Maorong Wang.

Author 3 - Zhiwu Dai.

Author 4 - Song Liang.

Author 5 - Yan Wen.