INPLASY PROTOCOL

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None declared.

Reliability of the evidence to guide decision-making in Panax notoginseng saponins for acute ischemic stroke: A protocol for overview of systematic review and meta-analysis

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Review question / Objective: **As an adjuvant therapy widely used in acute ischemic stroke (AIS), PNS has been shown to be effective and has some clinical evidence. However, this evidence has not been evaluated, and this overview will systematically assess and synthesize existing evidence to better guide clinical decision-making.**
Eligibility criteria: **The inclusion criteria are as follows: (1) Study design: SRs/MAs based on randomized controlled trials on PNS intervention in AIS; (2) Study population: Participants were diagnosed with AIS according to any authoritative diagnostic criteria, regardless of gender, age, race, time of onset or source of cases; (3) The control group received conventional treatment, and CTs were considered to include thrombolytic drugs, antiplatelet drugs, anticoagulant drugs, statins, neuroprotectants, and antihypertensive and collateral circulation drugs; (4) Outcomes: The primary outcomes were the proportion of recurrent ischemic stroke, symptomatic intracerebral hemorrhage, and all-cause mortality. Secondary outcomes were functional improvement, as measured by a validated Barthel index or other scales; quality of life, as assessed by a 36-item Short-Form Health Survey; and frequency and severity of adverse events.The exclusion criteria were as follows: (1) Animal studies; (2) Overviews, network MAs, and narrative reviews; (3) Studies in which the required data were unavailable; (4) Conference abstract.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 June 2022 and was last updated on 29 June 2022 (registration number INPLASY202260108).

INTRODUCTION

Review question / Objective: **As an adjuvant therapy widely used in acute ischemic stroke (AIS), PNS has been shown to be effective and has some clinical evidence. However, this evidence has not been evaluated, and this overview will**

systematically assess and synthesize existing evidence to better guide clinical decision-making.

Condition being studied: Acute ischemic stroke (AIS) is a dangerous cerebrovascular disease that causes irreversible damage to our brains [1]. Its pathogenesis is sudden occlusion of cerebral arteries, leading to cerebrovascular circulation dysfunction and irreversible neuronal necrosis [2]. AIS accounts for about 80% of all stroke cases and is characterized by neurological dysfunction due to focal occlusion or narrowing of arteries in the brain [3]. The incidence of AIS is high, and the prognosis is poor if not treated in time. According to epidemiological studies, there are about 17 million [4] AIS patients in the world every year, and 6.2 million people die from AIS [5]. In addition, the huge medical expenses consumed by AIS have brought a heavy burden to society and families [6]. Currently, routine treatments recommended by clinical practice guidelines include thrombolytics, antiplatelet drugs, anticoagulants, and neurotrophic drugs [7]. But there are also side effects and resistance, such as cerebral hemorrhage after thrombolysis [8] and clopidogrel resistance [9]. The shortcomings of these treatments have forced researchers to explore other treatment options for AIS to improve efficacy and prognosis. Panax notoginseng is the root of Panax notoginseng (Burk.) F. H. Chen, a traditional medicinal material with a long history of clinical application in traditional Chinese medicine since the Ming Dynasty [10]. Panax notoginseng saponins (PNS), an active ingredient extracted from the Chinese herbal medicine Panax notoginseng, has been widely used in the treatment of AIS in China. PNS includes notoginsenoside R1, ginsenoside Rg1, ginsenoside Re, ginsenoside Rb1, ginsenoside Rd-qt [11]. Pharmacological experiments to study the mechanism of action of PNS show that it has the effect of resisting ischemia-reperfusion injury [12]. Among other things, PNS can increase blood flow, inhibit inflammation and platelet aggregation, and reduce oxidative stress [13,14]. In recent years, several systematic reviews (SRs)/meta-analyses (MAs) of PNS therapy for AIS have been published. SRs/MAs are considered reliable criteria for assessing the effectiveness of therapeutic interventions, but their methods must strictly adhere to a set of guidelines to minimize bias in answering specific research questions [15]. However, a large proportion of SRs/MAs authors do not strictly adhere to the above criteria, which can lead to low-quality reviews and difficulty in providing convincing results and conclusions. Therefore, it is necessary for us to conduct a scientific evaluation of the relevant SRs/MAs of PNS in the treatment of AIS to explain the reliability of the clinical use of PNS in the treatment of AIS.

METHODS

Participant or population: Participants were diagnosed with AIS according to any authoritative diagnostic criteria, regardless of gender, age, race, time of onset or source of cases.

Intervention: The control group received conventional treatment, and CTs were considered to include thrombolytic drugs, antiplatelet drugs, anticoagulant drugs, statins, neuroprotectants, and antihypertensive and collateral circulation drugs.

Comparator: The control group received conventional treatment, and CTs were considered to include thrombolytic drugs, antiplatelet drugs, anticoagulant drugs, statins, neuroprotectants, and antihypertensive and collateral circulation drugs.

Study designs to be included: SRs/MAs based on randomized controlled trials on PNS intervention in AIS.

Eligibility criteria: The inclusion criteria are as follows: (1) Study design: SRs/MAs based on randomized controlled trials on PNS intervention in AIS; (2) Study population: Participants were diagnosed with AIS according to any authoritative

diagnostic criteria, regardless of gender, age, race, time of onset or source of cases; (3) The control group received conventional treatment, and CTs were considered to include thrombolytic drugs, antiplatelet drugs, anticoagulant drugs, statins, neuroprotectants, and antihypertensive and collateral circulation drugs; (4) Outcomes: The primary outcomes were the proportion of recurrent ischemic stroke, symptomatic intracerebral hemorrhage, and all-cause mortality. Secondary outcomes were functional improvement, as measured by a validated Barthel index or other scales; quality of life, as assessed by a 36-item Short-Form Health Survey; and frequency and severity of adverse events.The exclusion criteria were as follows: (1) Animal studies; (2) Overviews, network MAs, and narrative reviews; (3) Studies in which the required data were unavailable; (4) Conference abstract.

Information sources: The literature is retrieved in Cochrane Library, PubMed, Web of Science, EMBASE, CNKI, Wanfang Database, SinoMed, Chongqing VIP.

Main outcome(s): The primary outcomes were the proportion of recurrent ischemic stroke, symptomatic intracerebral hemorrhage, and all-cause mortality.

Additional outcome(s): Secondary outcomes were functional improvement, as measured by a validated Barthel index or other scales; quality of life, as assessed by a 36-item Short-Form Health Survey; and frequency and severity of adverse events.

Quality assessment / Risk of bias analysis: Assessment of reporting quality - The list of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [21] will be used to assess the quality of each SR/MA report according to the following areas: (a) Title, (b) Abstract, (c) Introduction, (d) Methods, (e) Results, (f) Discussion, (g) Funding. It consists of 27 projects focused on reporting methods and results of meta-analyses. Each item is considered "Yes" (full report), "Partial Yes" (partially reported), or "No" (not reported), depending on the completeness of the project information report. Assessment of quality of evidence - The Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system [22] will be used to assess the quality of evidence for the included SRs/MAs, downgrading from 5 areas: study limitation, inconsistency, indirectness, imprecision, and publication bias.

Strategy of data synthesis: NA.

Subgroup analysis: NA.

Sensitivity analysis: NA.

Country(ies) involved: China.

Keywords: Panax Notoginseng Saponins; Acute Ischemic Stroke; Randomised Controlled Trials; Meta-Analyses; Systematic Reviews; Overview.

Contributions of each author:
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