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Buyang Huanwu Decoction for cerebral infarction and intracerebral haemorrhage: a scoping review of differential mechanisms, clinical safety, and precision-use boundaries, with an optional critical appraisal and a hypothesis-generating research agenda

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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Completed but not published.

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 26 October 2026 and was last updated on 26 October 2026.

INTRODUCTION

Review question / Objective (1) What are the mechanistic actions of BYHWD in cerebral infarction and in intracerebral haemorrhage (ICH), and which pathways are shared or divergent between the two stroke subtypes?

(2) What is the evidence for a differential effect of BYHWD on neurorepair versus bleeding risk, and how strong is that evidence?

(3) What is the clinical efficacy and safety evidence for BYHWD in cerebral infarction and in ICH, respectively?

(4) On the basis of the mapped evidence, can a precision-use research agenda (time window, coagulation status, imaging and syndrome differentiation) be proposed, and what are its validation requirements?

Rationale Buyang Huanwu Decoction (BYHWD), a classic qi-tonifying and blood-activating formula, is widely used in post-ischaemic stroke rehabilitation

but remains controversial in intracerebral haemorrhage (ICH) because of its pro-angiogenic and antithrombotic properties. The same blood-activating actions that promote recovery after ischaemic stroke may, in principle, increase bleeding risk in ICH. This clinical equipoise - between established benefit in ischaemic stroke and unquantified risk in ICH - motivates the present review. A scoping review is appropriate because the aim is to map the breadth of mechanistic and clinical evidence across both stroke subtypes, to identify research gaps, and to propose a testable, hypothesis-generating research agenda, rather than to estimate a single pooled effect.

Condition being studied Cerebral infarction (ischaemic stroke) and intracerebral haemorrhage (ICH).

METHODS

Search strategy Databases: PubMed, Embase, Web of Science, CNKI, Wanfang, VIP.

Search period: each database from inception to July 2026.

Language: English and Chinese (bilingual search to remediate language bias).

Reference lists of included records were screened manually.

The complete search strategies with per-database record counts are provided as Supplementary File 1 of the review.

Participant or population Human patients or animal models with cerebral infarction (ischaemic stroke) or intracerebral haemorrhage (ICH).

Intervention Buyang Huanwu Decoction (BYHWD), a classic qi-tonifying and blood-activating formula, used as the whole formula (original composition or documented modification), as clearly BYHWD-derived preparations, or as characterised constituents of its seven component herbs (classified as component-level mechanistic evidence), alone or with conventional therapy.

Comparator Not applicable. This is a scoping review based on the PCC (Population–Concept–Context) framework and therefore has no predefined comparator. Where present, the comparators/controls of the included studies (e.g., conventional Western medicine treatment, placebo, no treatment, vehicle, sham surgery, or single-arm studies without a control) will be described descriptively during data charting.

Study designs to be included Randomised controlled trials, non-randomised clinical studies, systematic reviews/meta-analyses, and mechanistic studies (animal, in vitro, omics and network-pharmacology studies) reporting efficacy, safety or mechanistic outcomes, published as full-length peer-reviewed journal articles in English or Chinese.

Eligibility criteria Population

Human patients or animal models with cerebral infarction (ischaemic stroke) or intracerebral haemorrhage (ICH).

Concept / intervention

Studies of the whole BYHWD formula (original composition or documented modification), clearly BYHWD-derived preparations, or characterised constituents of its seven component herbs (classified as component-level mechanistic evidence), used alone or with conventional therapy.

Outcomes include efficacy, safety and mechanistic endpoints.

Context

No restriction by country or cultural background.

Information sources Databases: PubMed, Embase, Web of Science (English); CNKI, Wanfang, VIP (Chinese). Each database was searched from its inception to July 2026, using tailored title/abstract strategies. Reference lists of included records were also screened manually. The bilingual (English and Chinese) search was designed to remediate language bias, because BYHWD safety data in ICH are largely absent from the English-language literature. Complete search strategies with per-database record counts are provided in Supplementary File 1 of the review.

Main outcome(s) This scoping review does not designate a single primary outcome. The main outcome domains mapped are: (1) efficacy outcomes (neurological function, haematoma absorption, functional recovery); (2) safety outcomes (bleeding-related adverse events, haemorrhagic transformation, coagulation parameters); and (3) mechanistic outcomes (pathway modulation, biomarkers, and histological/imaging endpoints).

Data management A standardised, pilot-tested charting form will capture: bibliographic data (first author, year, country, language); evidence domain; study design; stroke subtype and phase; intervention (whole formula vs component-level; dosage; timing); comparator/control (if applicable); population/sample; primary outcome domains; key mechanistic pathways; and risk-of-bias ratings. Two reviewers will chart independently, with discrepancies resolved by discussion and a third reviewer.

Quality assessment / Risk of bias analysis

Optional critical appraisal: GRADE for human clinical evidence, and design-specific risk-of-bias tools (Cochrane RoB 2 for randomised trials, ROBINS-I for non-randomised studies, SYRCLE for animal studies). This appraisal is an optional, JBI-aligned enhancement and is not used to generate practice recommendations.

Strategy of data synthesis Descriptive synthesis using inductive thematic analysis. Each record will be assigned to one of four evidence domains (D1 human clinical studies; D2 systematic reviews/meta-analyses; D3 animal studies; D4 in vitro/omics/network pharmacology), and three attribution rules will govern the synthesis: formula-level clinical claims require D1/D2 evidence;

component-level evidence is used only for mechanistic plausibility; and studies of other formulae are retained solely as indirect contextual comparators.

Subgroup analysis Evidence will be synthesised by stroke subtype (cerebral infarction vs ICH), evidence domain, study design, and language (English vs Chinese).

Sensitivity analysis Not applicable. This scoping review does not perform a meta-analysis and therefore does not include sensitivity analyses.

Language restriction English and Chinese only.

Country(ies) involved china.

Keywords Buyang Huanwu Decoction; neurorepair; bleeding risk; cerebral infarction; intracerebral haemorrhage; scoping review.

Dissemination plans The completed review will be submitted for publication in the Journal of Functional Foods, with supplementary materials made available with the article.

Contributions of each author

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