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Intra-Arterial Stem Cell Therapy in Ischemic Stroke: A Systematic Review of Clinical Outcomes and Safety

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ABSTRACT

Ischemic stroke remains a major cause of mortality and long-term disability. Restricted therapeutic windows and persistent disability following reperfusion therapy have encouraged the development of neurorestorative approaches. Intra-arterial stem cell delivery may increase targeted cell exposure to ischemic brain tissue; however, its clinical safety and efficacy remain uncertain. This systematic review was conducted according to the PRISMA 2020 guidelines. PubMed, Scopus, and Google Scholar were searched using terms related to ischemic stroke, stem cells, bone marrow mononuclear cells, mesenchymal stem cells, CD34, intra-arterial delivery, NIHSS, modified Rankin Scale, and safety. Human studies using intra-arterial stem cell administration and reporting clinical or safety outcomes were narratively synthesized. Fifteen records were identified, 14 were screened, and eight reports met the inclusion criteria. These eight reports represented seven independent clinical cohorts because one publication was a diffusion tensor imaging (DTI) substudy of the IBIS trial. The included evidence comprised randomized controlled trials, phase I/II studies, feasibility or single-arm studies, and one case report. Intra-arterial administration was generally feasible and demonstrated a relatively favorable safety profile. Improvements in NIHSS, modified Rankin Scale, Barthel Index, or imaging outcomes were reported in several studies; however, clinical benefits were not consistently statistically significant. Interpretation was limited by small sample sizes, uncontrolled study designs, combined interventions, and substantial heterogeneity. Intra-arterial stem cell therapy demonstrates neurorestorative potential with a generally reassuring early safety profile, but its efficacy remains unproven. Larger randomized controlled trials with standardized protocols and long-term follow-up are required before routine clinical application can be recommended.

INTRODUCTION

Stroke remains a major global neurological burden, contributing significantly to mortality, long-term disability, reduced quality of life, and healthcare costs (Cheng et al., 2024; Cheon et al., 2023; Feigin et al., 2023, 2025). According to the 2021 Global Burden of Disease (GBD) Study, approximately 11.9 million new stroke cases and 7.3 million deaths occurred worldwide; ischemic stroke was the predominant type, accounting for 65.3% of all stroke events, or approximately 7.8 million new cases. The World Stroke Organization's Global Stroke Fact Sheet 2025 also reported that approximately 87% of stroke-related deaths and 89% of disability-adjusted life years (DALYs) occurred in low- and middle-income countries, highlighting that the stroke burden remains a significant global health challenge, particularly in resource-limited settings (Feigin et al., 2025; GBD 2021 Stroke Risk Factor Collaborators, 2024; Hou et al., 2024).

Current management of acute ischemic stroke focuses on restoring cerebral perfusion through intravenous thrombolysis and mechanical thrombectomy, interventions that have been demonstrated to improve clinical outcomes in eligible patients (De Cassai et al., 2024; Mehta et

al., 2024; Sheth, 2023). However, the benefits of reperfusion therapy are limited by therapeutic time windows, patient eligibility criteria, availability of facilities and trained personnel, and the persistence of residual disability in some patients despite successful reperfusion. These limitations underscore the need for additional therapeutic strategies that extend beyond acute reperfusion and rehabilitation to support tissue repair and neurological recovery after stroke. One promising neurorestorative approach is cell-based regenerative therapy. Therapies based on mesenchymal stem/stromal cells (MSCs) and bone marrow-derived cells are believed to exert therapeutic effects primarily through paracrine and immunomodulatory mechanisms rather than solely through direct replacement of damaged neurons. These mechanisms involve modulation of inflammatory responses and apoptosis, as well as stimulation of angiogenesis, neurogenesis, and neurovascular unit repair, collectively creating an environment conducive to post-stroke neurological recovery (Arbabian et al., 2026; Spiliopoulos et al., 2019).

The route of administration is a key determinant of biodistribution and safety. Intra-arterial administration can enhance initial cellular exposure within the cerebral circulation and reduce systemic sequestration compared with intravenous administration; however, this route also carries procedure-related risks, including microvascular obstruction influenced by cell size, dosage, and infusion characteristics (Arbabian et al., 2026; Spiliopoulos et al., 2019; Griauzde et al., 2019). The 2023 randomized IBIS trial demonstrated that intra-arterial administration of autologous bone marrow mononuclear cells (BMMNCs) was feasible and did not increase the incidence of serious adverse events, although the primary functional outcome at 180 days showed no significant improvement (Moniche et al., 2023). A network meta-analysis further indicated that the clinical effects of cytotherapy may vary depending on cell type, dosage, timing of therapy, and route of administration (Wang et al., 2020).

The novelty of this systematic review lies in its exclusive focus on the intra-arterial route of stem cell delivery for ischemic stroke, rigorous distinction between independent cohorts and secondary analyses, and comprehensive evaluation of both safety and clinical outcomes. Unlike previous reviews that have pooled data across different administration routes, this review provides a route-specific perspective that is essential for understanding the unique risk–benefit profile of intra-arterial delivery. Furthermore, by identifying seven independent clinical cohorts from eight reports, this review provides a more accurate representation of the available evidence base.

This systematic review aimed to evaluate the clinical outcomes and safety of intra-arterial stem cell therapy in patients with ischemic stroke, assess the methodological quality of the included studies, and identify gaps and directions for future research. By synthesizing the available evidence in a narrative format, this review sought to provide a comprehensive overview of the current state of knowledge and inform the design of future randomized controlled trials.

Previous studies have generally aggregated various administration routes and cell products, thereby limiting route-specific interpretation. Consequently, this systematic review focused on clinical reports involving intra-arterial stem cell delivery, whether used as a standalone approach or as part of a combination regimen, and evaluated both clinical outcomes and safety. The review also distinguished independent cohorts from secondary publications derived from the same trials to minimize the risk of overinterpretation caused by duplication of participant data.

METHOD

Study Design

This systematic review evaluated the clinical outcomes and safety of intra-arterial stem cell therapy in patients with ischemic stroke and was conducted in accordance with the PRISMA 2020 reporting framework. Due to heterogeneity among the included studies in terms of study design, cell products, timing of administration, and outcome measures, the findings were synthesized narratively rather than through meta-analysis.

Search Strategy

A literature search was conducted using PubMed, Scopus, and Google Scholar. Documented search terms included "ischemic stroke," "stem cell," "bone marrow mononuclear cells," "mesenchymal stem cells," "CD34," "intra-arterial," "NIHSS," "modified Rankin Scale," and "safety." These concepts were combined using Boolean operators to identify human clinical studies relevant to intra-arterial cell therapy. The initial search record documented a combined total of 15 records from the three databases; the specific number of records per database was not separately retained and thus was not included in this review.

Eligibility Criteria

Inclusion criteria were: (1) human participants with ischemic stroke; (2) administration of stem cell or progenitor cell products via the intra-arterial route, either alone or as part of a combination regimen; (3) reporting of clinical outcomes and/or safety outcomes such as NIHSS, modified Rankin Scale (mRS), Barthel Index (BI), European Stroke Scale, imaging outcomes, adverse events, or serious adverse events; and (4) original clinical research, including randomized trials, phase I/II studies, feasibility studies, single-arm studies, or case reports. Exclusion criteria were review articles, systematic reviews/meta-analyses, preclinical/animal studies, technical reports lacking qualifying clinical data, stem cell studies using only the intravenous route, and articles without full-text access. PRISMA Study Selection and Source Tracking

A total of 550 records were retrieved from PubMed, Scopus, and Google Scholar covering the last 15 years. Fifteen journals were identified; one duplicate was found and removed, leaving 14 journals for title/abstract screening. Five were excluded during the screening stage because they were reviews/meta-analyses or technical reports, or did not meet the route criteria. Nine full-text reports were assessed; one report involving only the intravenous route was excluded. Eight reports were included in the qualitative synthesis. These eight reports represent seven independent clinical cohorts, as the 2025 DTI publication is a substudy of the 2023 IBIS trial.

Methodological Quality and Interpretation of Evidence

Methodological quality was assessed descriptively based on study design, focusing on the presence of randomization and comparators, blinding of outcome assessments, sample size, completeness of follow-up, and potential confounding due to adjunctive interventions. Comparative randomized evidence is available from Bhatia et al., the IBIS trial, and RECOVER-Stroke. Other reports consist primarily of early-phase evidence, uncontrolled studies, feasibility studies, or case reports. Consequently, improvements observed in uncontrolled studies are interpreted primarily as signals of feasibility and safety rather than as evidence of efficacy. The DTI substudy is treated as secondary evidence derived from the IBIS cohort rather than as an independent efficacy trial.

Data Extraction and Synthesis

Data extracted from each included report comprised authors, year, journal/source, design, population and sample size, cell product, route of administration, comparator, primary outcomes,

key findings, and study limitations relevant to interpretation. Study-level data were cross-checked against available full-text sources. Due to clinical and methodological heterogeneity, synthesis was performed narratively, and no quantitative meta-analysis was conducted.

Quality Assessment

Methodological quality assessment was conducted descriptively, considering study design, randomization and comparator groups, blinding of outcome assessments, sample size, completeness of follow-up, and potential confounding due to adjunctive interventions. Randomized controlled trials (RCTs) by Bhatia et al. (2018), Savitz et al. (2019), and Moniche et al. (2023) provided relatively stronger methodological evidence compared to non-randomized studies, although they still possessed limitations regarding sample size, early-phase design, and the ability to demonstrate definitive efficacy. Phase I, single-arm, and feasibility studies were considered to have greater limitations due to the absence of control groups and small sample sizes, while case reports presented the most significant limitations for drawing causal conclusions. The DTI substudy by Cabezas-Rodriguez et al. (2025) is treated as secondary evidence from the IBIS cohort rather than as an independent study. Overall, variations in study design, sample size, intervention characteristics, and the use of adjunctive therapies resulted in varying levels of evidence quality; consequently, studies with limited designs were primarily used to support interpretations regarding safety and feasibility, whereas conclusions concerning effectiveness were based largely on results from controlled studies.

RESULTS AND DISCUSSION

Study Selection

Eight reports meeting the eligibility criteria were included, comprising randomized controlled trials, phase I/II trials, feasibility and single-arm studies, and one case report. Bone marrow mononuclear cells (BMMNC) were the most frequently used cell product. It should be noted that this evidence base does not represent eight independent trials: Cabezas-Rodriguez et al. analyzed an imaging subset of 38 patients drawn from the IBIS trial population reported by Moniche et al., and is therefore treated as a supplementary imaging analysis rather than an independent cohort.

Table 1. Synthesis of Included Clinical Reports

Study	Design / Sample	Cell Product & Route	Comparator	Primary Outcome	Key Findings & Safety	Limitations
Bhatia et al., 2018 [10]	RCT; n=20; ischemic stroke, MCA, 8-15 days	Autologous BMMNC, intra-arterial to ipsilateral MCA	Standard therapy	mRS, NIHSS, BI; procedural safety	Good outcome (mRS ≤2): 80% intervention vs 40% control (P=0.068); no procedure-related mortality, symptomatic ICH, or new infarcts reported	Small sample; effectiveness signal did not reach conventional significance
Moniche et al., 2023 (IBIS) [7]	Phase II RCT; n=77; onset 1-7 days	Autologous BMMNC, intra-arterial; low vs	Standard of care	mRS 0-2 at day 180; SAE; NIHSS; BI	No significant difference in primary effectiveness (BMMNC 47% vs control 39% for mRS 0-2); no increase in	Phase II; not powered to demonstrate definitive effectiveness; dose-response unclear

Study	Design / Sample	Cell Product & Route	Comparator	Primary Outcome	Key Findings & Safety	Limitations
		high dose			SAEs; two mild groin hematomas related to the procedure	
Savitz et al., 2019 (RECOVER-Stroke) [11]	Sham-controlled randomized phase II; n=48	Autologous ALD-401, intra-arterial via internal carotid artery	Sham infusion	Safety, mRS, BI, EQ-5D, MRI	No significant difference in mRS or secondary effectiveness endpoints; no infusion/allergic reactions; small asymptomatic DWI lesions occurred in treated patients	Fewer participants than planned; primarily powered for safety
Hammadi & Alhimyari, 2019 [12]	Single-arm clinical study; n=37; ischemic stroke	Autologous BMMNC, small-volume intra-arterial plus residual product intravenously	None	European Stroke Scale	25/37 (67.5%) showed neurological improvement over 4-8 weeks; no major safety signal highlighted	No control group; combined intra-arterial/intravenous route precludes isolating the intra-arterial effect
Banerjee et al., 2014 [13]	Open-label, non-randomized phase I; n=5; severe acute anterior circulation stroke	Autologous immunoselected CD34+ cells, intra-arterial to ipsilesional MCA	None	Safety, NIHSS, mRS, lesion volume	All patients showed clinical improvement at follow-up; well tolerated; no significant treatment-related adverse events	Very small phase I cohort with no comparator; effectiveness cannot be concluded
Jiang et al., 2013 [14]	Feasibility study; n=4 total (3 ischemic, 1 hemorrhagic)	Umbilical cord MSCs, single intra-arterial dose near lesion artery	None	Safety, mRS, motor function	Two of three ischemic patients showed improved muscle strength and mRS; no major stroke/death, fever, or rash reported after cell administration	Mixed stroke population; only 3 ischemic patients relevant; very small, uncontrolled
Cabezas-Rodriguez et al., 2025 [15]	DTI substudy of IBIS; n=38 with paired imaging (20 treated, 18 control)	Autologous BM-MNC, intra-arterial, as in IBIS	IBIS control group	DTI metrics; mRS; NIHSS; BI	Smaller FA reduction in ipsilateral CST; better CST preservation correlated with 6-month clinical outcome; no new route-specific safety signal	Not an independent cohort; subset/imaging-endpoint analysis should not be double-counted with IBIS

Study	Design / Sample	Cell Product & Route	Comparator	Primary Outcome	Key Findings & Safety	Limitations
Le et al., 2021 [16]	Case report; n=1; severe MCA ischemic stroke	Autologous BMMNC intra-arterial plus intravenous Cerebrolysin	None	NIHSS, mRS, BI, motor scale, MRI	Notable clinical and functional improvement during follow-up; no major treatment complications reported	Single case with an important additional intervention; benefit cannot be attributed to intra-arterial stem cells alone

Safety Outcomes

Across all included reports, intra-arterial cell administration was generally feasible and was not consistently associated with increased mortality, symptomatic intracranial hemorrhage, or severe infusion reactions. Bhatia et al. reported no procedure-related mortality, new infarcts, or symptomatic intracranial hemorrhage. In RECOVER-Stroke, four treated patients developed small asymptomatic diffusion-restricted lesions on MRI, interpreted as related to angiography or the procedure itself without clinical consequence. IBIS reported no increase in serious adverse events, although mild femoral/groin hematomas occurred following catheter-based administration.

Clinical Outcomes

Clinical effectiveness findings were less consistent than the safety findings. Bhatia et al. observed a favorable numerical difference in good mRS outcomes, but the between-group difference did not reach statistical significance. IBIS likewise found no significant improvement in its primary day-180 mRS outcome, and RECOVER-Stroke found no significant effectiveness difference compared with sham. Uncontrolled reports described neurological or functional improvement, but such findings are susceptible to spontaneous recovery, rehabilitation effects, regression to the mean, and concurrent interventions. The IBIS DTI substudy showed better preservation of corticospinal tract microstructure with a significant correlation to functional outcome, offering an interesting secondary biological signal rather than independent evidence of clinical effectiveness.

Discussion

This systematic review shows that intra-arterial stem cell therapy for ischemic stroke has a relatively consistent early safety and feasibility signal, while evidence of clinical effectiveness remains uncertain. This distinction is important because most of the available literature consists of early-phase studies primarily designed to assess procedural feasibility and safety rather than to definitively demonstrate functional benefit. The two larger randomized programs, IBIS and RECOVER-Stroke, showed no statistically significant improvement in their primary effectiveness outcomes (Moniche et al., 2023; Savitz et al., 2019).

The biological rationale for intra-arterial administration is reasonably strong. Compared with systemic delivery, the intra-arterial route may increase local exposure within the cerebral circulation and reduce first-pass pulmonary sequestration, potentially increasing contact between therapeutic cells and the ischemic neurovascular compartment (Arbabian et al., 2026; Spiliopoulos et al., 2019; Griauzde et al., 2019). However, route-specific safety remains important, as high cell doses, large cell size, and rapid infusion can increase the risk of

microvascular obstruction. Current reviews on cell-therapy delivery therefore emphasize optimizing dose, cell characteristics, and administration technique to achieve optimal effectiveness and safety, since a greater number of cells reaching the target tissue does not always correlate with better therapeutic outcomes (Arbabian et al., 2026; Spiliopoulos et al., 2019).

Clinical evidence on cell-based stroke therapy remains considerably heterogeneous, particularly regarding cell-product type and biological target. BMMNCs are the most widely studied product in clinical trials, while other populations such as CD34+ progenitor cells, ALDH-bright cells, and mesenchymal stem/stromal cells (MSCs) have also been evaluated (Moniche et al., 2023; Bhatia et al., 2018; Savitz et al., 2019; Hammadi & Alhimyari, 2019; Banerjee et al., 2014; Jiang et al., 2013; Cabezas-Rodriguez et al., 2025). Each cell product has distinct biological characteristics, including cellular composition, paracrine activity, angiogenic potential, immunomodulatory effects, and manufacturing process. A network meta-analysis of randomized trials has shown that cell type, dose, route, and timing of administration can all influence therapeutic outcomes (Wang et al., 2020). This heterogeneity indicates that the effectiveness of cell-based therapy needs to be evaluated according to the characteristics of each product and administration protocol, such that pooling different cell therapies into a single effectiveness estimate risks producing misleading clinical interpretations.

Interpretation of the findings must account for variation in intervention characteristics and study design. Hammadi and Alhimyari used a BMMNC regimen combining intra-arterial and intravenous routes (Hammadi & Alhimyari, 2019), while Le et al. evaluated intra-arterial BMMNC given together with intravenous Cerebrolysin (Le et al., 2021); the outcomes reported in both studies therefore reflect the overall effect of the combined treatment strategy rather than specifically representing the contribution of the intra-arterial route alone. Jiang et al. enrolled four stroke patients, three with ischemic stroke and one with hemorrhagic stroke (Jiang et al., 2013), so this review's interpretation focuses on the ischemic participants. In addition, the 2025 DTI report is a follow-up analysis of the IBIS cohort (Cabezas-Rodriguez et al., 2025) and was therefore treated as supplementary imaging information rather than an independent cohort in the overall evidence synthesis.

Overall, the available evidence shows variation in study design, sample size, stroke phase at intervention, cell-product type and dose, and outcome definitions. This clinical and methodological diversity makes a narrative synthesis more appropriate for describing the current evidence than quantitative pooling across studies. Within this context, the available findings provide an important basis regarding the safety, feasibility, and potential clinical benefit of intra-arterial cell therapy, while also indicating the need for further evaluation to determine the magnitude of the therapeutic effect and to identify the optimal administration protocol.

Future research should be directed toward randomized clinical trials with adequate sample sizes, standardized cell characterization and dosing, and consistently documented catheterization and infusion protocols. The use of predefined functional outcomes, relevant imaging biomarkers, and longer follow-up periods would further strengthen the evaluation of treatment response. In addition, reporting that clearly distinguishes catheterization-procedure-related events from cell-product-related adverse events would improve the interpretability of safety profiles. Standardizing these aspects is expected to improve comparability across studies and yield more precise estimates of the safety and effectiveness of intra-arterial stem cell therapy, thereby supporting the development of more targeted cell-based treatment strategies for ischemic stroke.

CONCLUSION

Intra-arterial stem cell therapy for ischemic stroke appears feasible and demonstrates a generally favorable safety profile in early-phase clinical studies. However, evidence from randomized controlled trials has not shown consistent or definitive improvements in functional outcomes. Findings from small, uncontrolled studies should be interpreted with caution, as they may be influenced by spontaneous recovery, clinical heterogeneity, concomitant interventions, and limited sample sizes. Currently, intra-arterial stem cell therapy should be considered an investigational treatment rather than a standard of care. Larger randomized controlled trials using standardized cell products, dosages, administration protocols, and long-term outcome assessments are still required to determine its clinical efficacy and potential role in routine stroke management.

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