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Systematic review and meta-analysis of the efficacy and safety of batroxobin as an adjunctive therapy for sudden deafness: Evidence synthesis based on 18 randomized controlled trials

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ADMINISTRATIVE INFORMATION

Support - None.

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 12 June 2026 and was last updated on 12 June 2026.

INTRODUCTION

Review question / Objective Review question: In patients with sudden sensorineural hearing loss (SSNHL), does treatment with batroxobin as an adjunctive therapy to basic conventional treatment improve the total effective rate, pure-tone average (PTA), and safety compared to basic treatment alone?
Objective: To systematically evaluate the clinical efficacy and safety of batroxobin as an adjunctive treatment for patients with sudden deafness, and to synthesize the existing evidence from 18 randomized controlled trials (RCTs) through meta-analysis.

Condition being studied Sudden deafness is one of the common emergencies in otorhinolaryngology. The etiology is not yet clear. It is generally believed that the dysfunction of the inner ear circulation is the main pathogenic factor. The blood supply of the inner ear comes from the terminal branch of the basilar artery. The lack of collateral circulation is prone to tissue ischemiaand hypoxia, which leads to hearing loss. Batroxobin is a thrombin-like drug that dissolves thrombus and improves microcirculation, which can effectively improve the blood supply of cochlea. Some studies have confirmed that batroxobin has good effect and less adverse reactions in the treatment of sudden deafness. Some studies have confirmed that it is not helpful for the treatment of sudden deafness. At present, there are many studies on batroxobin in the treatment of sudden deafness. However, due to the lack of standardization of clinical research methods and evaluation methods, the clinical treatment effect is still inconclusive, which affects the authenticity of the research results to a certain extent.Therefore, this study used systematic review and meta-analysis to evaluate the efficacy and safety of batroxobin as an additional treatment for sudden deafness, and to provide evidence-based basis for clinical treatment.

METHODS

Participant or population Patients clearly diagnosed with sudden deafness according to authoritative guidelines (e.g., the 2005 or 2015 Chinese guidelines for sudden deafness).

Intervention The experimental group is treated with batroxobin in addition to the conventional basic treatment (such as systemic or local glucocorticoids, microcirculation-improving drugs, neurotrophic drugs, and symptomatic support).

Comparator The control group receives the identical conventional basic treatment without batroxobin.

Study designs to be included Only randomised controlled trial will be included.

Eligibility criteria 1.Patients diagnosed with sudden deafness based on standard guidelines.
2.The trial design was a randomized controlled trial (RCT).
3.The experimental group received batroxobin as an adjunctive to the control group's basic treatment.
4.The control group received identical basic treatment without batroxobin.
5.Reported at least one efficacy outcome (total effective rate or PTA improvement) or safety outcome.
6.Statistical efficacy must be evaluated per "person" rather than combining single and double ears and evaluating per "ear".

Information sources A comprehensive literature search covering 8 Chinese and English databases: CBM, CNKI, Wanfang, VIP, PubMed, EMBASE, Web of Science, and Cochrane Central Register of Controlled Trials (CENTRAL). The search also includes clinical trial registries (ChiCTR and ClinicalTrials.gov) from inception to March 11, 2026. Hand-searching of reference lists of included studies and relevant reviews will also be conducted.

Main outcome(s) Total effective rate.

Additional outcome(s) 1.Improvement in pure-tone average (PTA).

2.Incidence of adverse reactions.

Quality assessment / Risk of bias analysis The methodological quality and risk of bias of the included RCTs will be independently assessed using the Cochrane risk-of-bias tool (RoB tool).This tool evaluates bias across five domains:1. Bias arising from the randomization process – assessing whether the allocation sequence was properly generated and concealed;2. Bias due to devia tions from in tended interventions – examining adherence to the assigned intervention and management of crossover or non-adherence;3. Bias due to missing outcome data – evaluating the extent and handling of incomplete data;4. Bias in measurement of the outcome – determining whether outcome assessment was blinded and objective;5. Bias in selection of the reported result – checking for evidence of selective reporting of outcomes or analyses.For each domain, judgments will be made as "Low risk", "Some concerns", or "High risk" of bias, based on predefined signaling questions. Any discrepancies will be resolved through discussion or consultation with a third reviewer. A risk-of-bias summary figure will be generated to visually present the assessment results.

Strategy of data synthesis Data synthesis will be performed using RevMan 5.4 software. The Risk Ratio (RR) will be used for dichotomous variables (total effective rate, adverse reactions), and the Mean Difference (MD) will be used for continuous variables (PTA), both expressed with 95% confidence intervals (95% CI). Considering clinical and methodological heterogeneity, a random-effects model will be used for the main analysis to estimate the average intervention effect.

Subgroup analysis Subgroup analysis was performed according to the baseline medication regimen, and the groups using glucocorticoid alone, glucocorticoid combined with microcirculation improvement drugs, and microcirculation improvement drugs alone were specifically compared.

Sensitivity analysis A fixed-effects model will be used to conduct sensitivity analysis to evaluate the robustness of the primary meta-analysis results.

Country(ies) involved China.

Keywords batroxobin; sudden sensorineural hearing loss.

Contributions of each author
Author 1 - Shuxin Liao - Put forward research questions, design research programs, perform literature retrieval, literature screening, data extraction, bias risk assessment and statistical analysis, and write the first draft and later revision of the paper.
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Author 2 - Zhuoyi Chen - put forward the research questions, design the research plan, participate in the cross-check of literature double-blind screening, independent data extraction and quality evaluation as an independent second evaluator, assist in the operation of Meta-analysis software and chart making, and participate in the review and modification of the paper.
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Author 3 - Hao Xiong - Responsible for the overall conception and supervision of the project, providing clinical and methodological guidance, responsible for solving the academic differences in the process of literature screening and data extraction, reviewing and revising the core content of the paper, and responsible for the final draft.
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