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Comparative Botulinum Toxin Injection Strategies Beyond the Masseter for Bruxism: A Scoping Review

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Preliminary searches.

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 2 August 2026 and was last updated on 2 August 2026.

INTRODUCTION

Review question / Objective Review question: Among individuals with bruxism receiving botulinum toxin injections, how do masseter-only strategies compare with strategies that add or otherwise target other masticatory or related jaw muscles in terms of clinical, patient-reported, objective, and safety outcomes?
Objective: To map and describe comparative evidence on botulinum toxin injection strategies for bruxism, with particular emphasis on the incremental benefit of adding muscles beyond the masseter. The review will characterize study designs, participants, diagnostic definitions, toxin formulations, injected muscles, doses, injection points, guidance methods, comparators, follow-up periods, outcomes, and adverse events. Direct add-on comparisons will form the primary evidence map, whereas dose-escalating and alternative-muscle strategies will be synthesized separately. The review will examine whether anatomical targeting effects can be distinguished from differences in total toxin dose and identify priorities for future dose-matched comparative trials.

Background Bruxism is a repetitive jaw-muscle activity involving clenching or grinding of the teeth or bracing or thrusting of the mandible. It may occur during sleep or wakefulness and can be associated with jaw pain, tooth wear, impaired oral function, and reduced quality of life. Botulinum toxin has been investigated and used to reduce excessive masticatory-muscle activity, particularly when conventional treatments are insufficient.
The masseter is the most commonly injected muscle because of its major role in jaw closure and its accessibility. However, some protocols also target the temporalis, pterygoid, digastric, or other

muscles to achieve broader suppression of bruxism-related activity. Whether these additional injections provide clinically meaningful benefit beyond masseter-only treatment remains uncertain.

Interpretation of the available evidence is complicated by substantial variation in diagnostic criteria, injected muscles, toxin formulations, doses, injection techniques, outcome measures, and follow-up periods. In many comparative studies, broader injection patterns also involve higher total toxin doses, making it difficult to separate the effect of anatomical targeting from the effect of dose escalation.

Previous reviews have mainly assessed the overall efficacy and safety of botulinum toxin for bruxism. The incremental benefit of injecting muscles beyond the masseter has not been specifically mapped. This scoping review will therefore summarize comparative injection strategies, evaluate clinical, patient-reported, and objective outcomes, distinguish direct add-on comparisons from dose-escalating or alternative-muscle approaches, and identify priorities for future dose-matched trials using standardized bruxism definitions and clinically meaningful outcomes.

Rationale Botulinum toxin has been investigated as a potential treatment for bruxism, but the optimal injection pattern remains unclear. Although the masseter is the most commonly targeted muscle, some protocols also inject the temporalis, pterygoid, digastric, or other muscles. It is uncertain whether these broader strategies provide additional clinical benefit or merely increase treatment complexity, toxin exposure, cost, and the risk of adverse effects.

Existing reviews have mainly examined the overall effectiveness and safety of botulinum toxin rather than the incremental value of injecting muscles beyond the masseter. Comparative studies are limited and heterogeneous in bruxism definitions, injection sites, toxin formulations, doses, outcome measures, and follow-up periods. Importantly, additional-muscle protocols often use higher total toxin doses, making it difficult to distinguish the effect of anatomical targeting from dose escalation.

A scoping review is therefore appropriate to map the available comparative evidence, characterize injection strategies, and clarify the extent and nature of current knowledge. The review will distinguish direct add-on comparisons from dose-escalating and alternative-muscle strategies, summarize clinical, patient-reported, objective, and safety outcomes, and identify methodological limitations. The findings may support more rational muscle selection in clinical practice and guide future dose-matched trials using standardized diagnostic criteria and clinically meaningful outcomes.

METHODS

Strategy of data synthesis PubMed/MEDLINE, Scopus, CENTRAL, and WHO ICTRP will be searched from inception to the final search date, supplemented by backward and forward citation searching. Controlled vocabulary and free-text terms will cover bruxism, botulinum toxin, and relevant injected muscles. No restrictions will initially be applied by date, location, recruitment status, or follow-up. Records will be deduplicated, and two reviewers will independently perform screening, full-text assessment, and standardized data extraction, with disagreements resolved by discussion or a third reviewer. Trial registrations, protocols, conference abstracts, and publications relating to the same trial will be linked as reports of one underlying study. Published studies with outcome data will form the main synthesis, whereas eligible registry-only or protocol-only studies will be mapped separately using available descriptive information and will not contribute to conclusions on effectiveness or safety unless results are available. Extracted data will include study design, participant characteristics, bruxism definition, toxin formulation, injected muscles, dose, injection technique, comparator, follow-up, outcomes, and adverse events. Findings will be synthesized descriptively and grouped by masseter-only versus masseter plus additional muscles, dose-escalating multi-muscle strategies, alternative muscle-targeting strategies, and other relevant comparative approaches. Particular attention will be given to whether anatomical targeting effects can be distinguished from differences in total toxin dose. Meta-analysis is not planned because substantial clinical and methodological heterogeneity is anticipated. Methodological quality will be appraised independently by two reviewers using the appropriate JBI critical appraisal checklist for each study design. Appraisal findings will not determine eligibility but will be used to contextualize the evidence.

Eligibility criteria Eligible participants will be children or adults with sleep, awake, mixed, or unspecified bruxism, diagnosed using clinical criteria, questionnaires, electromyography, polysomnography, or other clearly reported methods. Studies of primary or secondary bruxism will be considered. Studies involving temporomandibular disorders, myofascial pain, neurological conditions, or other comorbidities will

be included only when bruxism is explicitly identified in the study population or when data for participants with bruxism can be extracted separately.

The concept of interest is the comparative use of botulinum toxin injection strategies that differ according to the muscles targeted. Eligible studies must compare masseter-only injection with injection into the masseter plus one or more additional muscles, such as the temporalis, medial or lateral pterygoid, digastric, suprahyoid, or other masticatory muscles. Dose-escalating multi-muscle protocols and comparisons between masseter-only injection and alternative non-masseter muscle strategies will also be included but synthesized separately. Randomized parallel-group trials, randomized crossover trials, and prospective non-randomized comparative interventional studies will be eligible. Single-arm, retrospective non-comparative, and case-report evidence will be excluded. Trial registrations, protocols, and conference abstracts meeting the same criteria will be retained and linked to related publications. Registry-only or protocol-only studies without results will be mapped descriptively but will not contribute to conclusions about effectiveness or safety.

Eligible outcomes may include bruxism frequency or intensity, electromyographic or polysomnographic measures, pain, bite force, jaw function, muscle activity or thickness, patient-reported improvement, satisfaction, quality of life, duration of effect, and adverse events. Studies will not be excluded solely because they report only one relevant outcome.

The review will include studies conducted in any clinical or research setting and in any country, without restrictions on botulinum toxin formulation, injection guidance method, dose, number of injection points, or follow-up duration. Studies will be excluded if they evaluate botulinum toxin only against placebo, no treatment, oral appliances, medication, physiotherapy, dry needling, or another intervention without comparing different muscle-targeting strategies. Single-arm studies, case reports, reviews, editorials, animal or laboratory studies, cosmetic masseter-reduction studies without bruxism, and studies of temporomandibular disorders or facial pain without an identifiable bruxism population will also be excluded.

Source of evidence screening and selection All identified records will be imported into reference-management software and duplicates will be removed before screening. Two reviewers will independently screen titles and abstracts against the predefined eligibility criteria. Before formal screening, the reviewers will pilot-test the criteria on a sample of records and refine the screening guidance if necessary. Records considered potentially eligible by either reviewer will proceed to full-text assessment.

The same two reviewers will independently assess the full texts of potentially eligible reports. Reasons for exclusion at the full-text stage will be recorded and reported in the PRISMA-ScR flow diagram. Trial registrations, protocols, conference abstracts, and journal publications referring to the same underlying study will be linked and treated as multiple reports of one study. When a potentially eligible report cannot be retrieved, reasonable attempts will be made through institutional library services, author contact, or other available sources, and unretrieved reports will be documented separately.

Disagreements at any stage will be resolved through discussion and consensus. When consensus cannot be reached, a third reviewer will adjudicate. The study-selection process will be documented using the PRISMA-ScR flow diagram, including the numbers of records identified, duplicates removed, records screened, full texts assessed, reports excluded with reasons, and studies included in the final review.

Data management Search results will be imported into EndNote and deduplicated before screening. Each record will receive a unique identification number, and multiple publications, conference abstracts, protocols, or registry entries relating to the same trial will be linked as reports of one underlying study. Screening decisions, reasons for full-text exclusion, and reviewer disagreements will be documented in a standardized spreadsheet. Data will be extracted using a pilot-tested form in Microsoft Excel, with predefined fields covering study characteristics, participants, diagnostic criteria, intervention and comparator details, injected muscles, toxin dose, outcomes, follow-up, and adverse events. Registry-only or protocol-only studies will be clearly distinguished from studies reporting outcome data. Electronic files will be stored in password-protected institutional storage accessible only to the review team, with regular backups and version control. Any amendments to screening criteria or the extraction form will be dated and documented.

Language restriction English.

Country(ies) involved Thailand.

Keywords Bruxism; sleep bruxism; botulinum toxin; masseter muscle; temporalis muscle;

pterygoid muscles; masticatory muscles; injection strategy; comparative study; scoping review.

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