



Effectiveness of botulinum toxins for sleep bruxism (Protocol)

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Abstract :

Objective: Determine the effectiveness of botulinum toxins (BoNT) in managing sleep bruxism in adults. The assessment of the efficacy and the safety of the BoNT intervention in the masticatory muscles is necessary to determine its role in the management of primary Sleep Bruxism (SB) in adults. Therefore, identifying all the relevant evidence will improve our current understanding of this procedure regarding doses, techniques, methods, and SB outcomes, as well as the effectiveness and associated adverse effects. **Methods:** Criteria for considering studies: Only randomized controlled clinical trials. **Types of participants:** Adults aged 18 years or older with primary sleep bruxism, assessed using polysomnography. **Types of**

interventions: Intramuscular injection of botulinum toxin in the masseter and/or temporalis muscles, either unilateral or bilateral, compared to placebo. Types of outcome measures: Bruxism events, dental/orofacial deleterious effects, oral health-related quality of life. Sleep quality, dental restorative failures, adverse effects. Measures of effect: differences between two means. Selection of studies: The titles and abstracts retrieved after the search strategy will be screened in duplicate by two independent reviewers. The risk of bias in included studies will be determined using the Cochrane risk of bias tool. Method for data synthesis if heterogeneity between studies is not relevant and the I^2 is less or equal to 40%, a fixed effect model will be implemented. A random effect model will be indicated if heterogeneity is detectable and I^2 is greater than 40%. The availability of data and heterogeneity between studies will be considered to perform a meta-analysis.