INPLASY PROTOCOL

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None declared.

Efficacy and safety of botulinum toxin type A in distraction osteogenesis of the lower extremities: a meta-analysis of randomized controlled trials

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Review question / Objective: **P: patients undergoing distraction osteogenesis; I: Botulinum neurotoxin after surgery; C: Placebo or interventions other than botulinum neurotoxin; O: pain, adverse event rate, infection of pin site.**
Condition being studied: **Patients undergoing lower limb distraction osteogenesis often suffer from pain, joint contracture, pin site infection and many other complications. Some believe that the relative slower lengthening of muscles compared with the bones plays a considerable role in the development of surgical complications. As botulinum neurotoxin (BoNT) can treat dynamic contracture and pain in patients with spasticity, we believe that BoNT may have a role in distraction osteogenesis.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 November 2021 and was last updated on 08 November 2021 (registration number INPLASY2021110027).

INTRODUCTION

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METHODS

Participant or population: Patients undergoing distraction osteogenesis.

Intervention: Botulinum neurotoxin after surgery.

Comparator: Placebo or interventions other than botulinum neurotoxin Placebo.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: Inclusion criteria were patients undergoing distraction osteogenesis and receiving botulinum toxin. We exclude articles not published in English, and nonrandomized controlled studies.

Information sources: Electronic databases (Pubmed, Medline, Web of Science), trial registers (Cochrane library), contact with authors if necessary.

Main outcome(s): Pain after surgery (during distraction phase, by VAS score).

Additional outcome(s): Pain after surgery (first day, by VAS score), pin site infection rate, adverse event rate.

Quality assessment / Risk of bias analysis: By Cochrane Risk of Bias tool.

Strategy of data synthesis: By random effects model.

Subgroup analysis: Random-effects meta-regression: Continuous variables: age, amount of lengthening Categorical variables: Dose of BoNT, single or multi-site study design.

Sensitivity analysis: We used the method of removing one trial at a time and analyzing the remaining trials to estimate whether the effect resulted from a single study.

Language: English.

Country(ies) involved: Republic of China, Taiwan.

Keywords: Botulinum neurotoxin; distraction osteogenesis; limb lengthening.

Contributions of each author:
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Author 3 - Pei-Chun Hsieh.
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