INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Comparative Effectiveness of Botulinum Toxin and Extracorporeal Shockwave Therapy for Post-stroke Spasticity: a Protocol for Systematic Review and Meta-analysis

Chang, KV[1].

Review question / Objective: **To investigate the comparative effectiveness of botulinum toxin (BoNT) injection vs. extracorporeal shockwave therapy (ESWT) in spasticity reduction on stroke survivors.**
Condition being studied: **Spasticity on hemiplegic limbs in patients with chronic stroke.**
Information sources: **A systemic literature search will be conducted in PubMed (US National Library of Medicine) and Embase (Wolters Kluwer Ovid) for RCTs investigating BoNT injection and ESWT for treatments of post-stroke spasticity. The reference lists or bibliographies of the available review articles and meta-analyses will be scrutinized for additional candidates. Case reports, case series, conference abstracts, animal studies or those performed in laboratory settings will be excluded from the present meta-analysis.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 July 2021 and was last updated on 07 July 2021 (registration number INPLASY202170018).

INTRODUCTION

Review question / Objective: **To investigate the comparative effectiveness of botulinum toxin (BoNT) injection vs. extracorporeal shockwave therapy (ESWT) in spasticity reduction on stroke survivors.**

Condition being studied: **Spasticity on hemiplegic limbs in patients with chronic stroke.**

METHODS

Participant or population: **Patients with chronic stroke.**

Intervention: BoNT and ESWT.

Comparator: Placebo injections, sham therapy, oral medications and physiotherapy.

Study designs to be included: Randomized controlled trial (RCT).

Eligibility criteria: (1) patients with post-stroke spasticity; (2) RCTs including at least two therapeutic arms comparing therapies among BoNT, ESWT or the control treatment; (3) the use of the Modified Ashworth Scale (MAS) for spasticity measurements.

Information sources: A systemic literature search will be conducted in PubMed (US National Library of Medicine) and Embase (Wolters Kluwer Ovid) for RCTs investigating BoNT injection and ESWT for treatments of post-stroke spasticity. The reference lists or bibliographies of the available review articles and meta-analyses will be scrutinized for additional candidates. Case reports, case series, conference abstracts, animal studies or those performed in laboratory settings will be excluded from the present meta-analysis.

Main outcome(s): The outcome is the weight mean difference (WMD) on the MAS of spasticity reduction in the short- and mid-term.

Quality assessment / Risk of bias analysis: The Cochrane Risk of Bias Tool for RCTs will be utilized for methodological quality appraisal.

Strategy of data synthesis: Regarding the pairwise meta-analysis, the random effect model will be used for data pooling. The Cochrane Q tests and I2 statistic will be employed to determine the heterogeneity of direct comparisons and significant heterogeneity is assumed in case of an I2 value >50%. A mixed treatment comparison with a generalized linear mixed model will be used for the network meta-analysis. The probability ranking metrics will be used to reflect clinically important relative differences on the outcomes. The publication bias will be examined by using Egger's regression test and the inspection of the distribution pattern of the effect size on the funnel plot. All the analyses will be performed using the statistical software package Stata (StataCorp. 2015. Stata Statistical Software: Release 14. StataCorp LP, College Station, TX, USA), and a p-value of < 0.05 will be considered statistical significance.

Subgroup analysis: The subgroup analysis may be performed according to the differences in the BoNT dosage and ESWT protocols.

Sensitivity analysis: The sensitivity analysis may be performed for outliers.

Language: No limitation of languages.

Country(ies) involved: Taiwan.

Keywords: botulinum toxin, extracorporeal shock wave therapy, stroke, spasticity.

Contributions of each author:
Author 1 - Ke-Vin Chang.