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ADMINISTRATIVE INFORMATION**Support** - None reported.**Review Stage at time of this submission** - Preliminary searches.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202510007**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 3 January 2025 and was last updated on 3 January 2025.**INTRODUCTION**

Review question / Objective Adult stroke survivors, no limits have been set on the type (infarct/haemorrhage), location (anatomical) or stage (acute/chronic) of the lesion. Patients with stable spasticity (no variability within 2 months before recruitment) in the upper and lower limb (at least grade 1 measured by the Modified Ashworth Scale [MAS]). Patients with fixed contractures (MAS grade 4) in the wrist or fingers and ankle or toes, bilateral hemiplegia and patients with malignant tumors, coagulopathy, pacemakers, or infections will be also excluded. Extracorporeal shock wave therapy (ESWT) is defined as a sequence of acoustic pulses characterized by high peak pressure (100 MPa), fast pressure rise (10 ns), short duration (10 ms), and an energy density ranging from 0.003 to 0.890 mJ/mm. There is two ESWT: focused shock wave therapy and radial shock wave therapy Routine rehabilitation treatment MAS,FMA,MBI,ROM.

Condition being studied Stroke is the primary cause of long-term disability in the United States and Europe. According to the World Health Organization, 15 million people suffer a stroke worldwide each year, with 5 million resulting in death and another 5 million leading to permanent disability. Spasticity, a neurological symptom frequently seen in stroke patients, is characterized by an increase in muscle tone and exaggerated tendon reflexes. Its prevalence is reported as 39% in patients who have had their first stroke within 12 months. Spasticity should be treated properly as it hinders normal movements, causes pain, and affects a patient's ability to carry out daily activities, significantly impacting their functional status and quality of life. Recent studies suggest that extracorporeal shock wave therapy is effective in treating spasticity and is being considered as a new treatment method.

METHODS

Participant or population Adult stroke survivors, no limits have been set on the type (infarct/haemorrhage), location (anatomical) or stage (acute/chronic) of the lesion. Patients with stable spasticity (no variability within 2 months before recruitment) in the upper and lower limb (at least grade 1 measured by the Modified Ashworth Scale [MAS]). Patients with fixed contractures (MAS grade 4) in the wrist or fingers and ankle or toes, bilateral hemiplegia and patients with malignant tumors, coagulopathy, pacemakers, or infections will be also excluded.

Intervention Extracorporeal shock wave therapy (ESWT) is defined as a sequence of acoustic pulses characterized by high peak pressure (100 MPa), fast pressure rise (10 ns), short duration (10 ms), and an energy density ranging from 0.003 to 0.890 mJ/mm. There is two ESWT: focused shock wave therapy and radial shock wave therapy.

Comparator Routine rehabilitation treatment.

Study designs to be included RCT.

Eligibility criteria Criteria for diagnosing stroke spasticity.

Information sources Embase, PubMed, Web of Science, Cochrane Library will be searched to include studies published until December 2024. Studies published in English and china will be included for this review.

Main outcome(s) MAS, FMA, ROM, MBI.

Quality assessment / Risk of bias analysis The same authors (RC, JC) independently will assess the methodological quality of the studies included in the review by means of the PEDro scale (Maher, 2006), with a possible scoring ranging from 0 to 10, where a higher score stands for better quality. If there is any disagreement other author (AG) will be discussed until consensus is reached.

Strategy of data synthesis Interventions. It will be reported by the Preferred Reporting Items for Systematic Review and Meta-Analysis

This systematic review will follow the recommendations of the Cochrane Handbook for systematic reviews of Protocols (PRISMA-P). Data will be entered into REVMAN software. We will provide summaries of intervention effects for each study by calculating risk ratios (for dichotomous outcomes) or standardized mean differences (for continuous outcomes). Heterogeneity will be

examined by visual inspection of forest plot, I^2 test and I^2 statistic. Sensitivity analysis will occur after the initial meta-analyses are completed. If more than 10 studies are included in the meta-analysis, a funnel plot test will occur to determine if small studies affected the overall outcome.

Subgroup analysis Frequency.

Sensitivity analysis Stata.

Country(ies) involved China.

Keywords stroke, Cerebrovascular accident, Cerebral stroke, Cerebrovascular apoplexy, Brain vascular accident, Cerebrovascular atroke, apoplexy, Acute stroke; Extracorporeal shock wave therapy, shock wave therapy, Extracorporeal high intensity focused ultrasound therapy, High intensity focused.

Contributions of each author

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