STUDY PROTOCOL with Statistical Analysis Plan

Official Study Title: Comparison of Focused versus Radial Extracorporeal Shock Wave Therapy on Gastrocnemius Spasticity in Children with Spastic Quadriplegic Cerebral Palsy: A Pilot Randomized Controlled Trial

NCT Number: not yet assigned

Document Date: 5 December 2025

Title: Comparison of Focused versus Radial Extracorporeal Shock Wave Therapy on Gastrocnemius Spasticity in Children with Spastic Quadriplegic Cerebral Palsy: A Pilot Randomized Controlled Trial

Objective:

- To compare the effectiveness of focused Extracorporeal Shock Wave Therapy (fESWT) versus radial Extracorporeal Shock Wave Therapy (rESWT) on gastrocnemius spasticity in children with spastic quadriplegic cerebral palsy (CP).
- To evaluate the durability of antispastic effects measured by the Modified Ashworth Scale (MAS).

Study Design:

- A prospective randomized controlled trial with two parallel groups.
- Two active comparator arms:
    - Arm 1: focused ESWT (fESWT)
    - Arm 2: radial ESWT (rESWT)
- Masking: Outcomes assessor (single-blind)
- Primary purpose: Treatment
- Location: Pediatric Outpatient Clinic of the Department of Physical Medicine and Rehabilitation, Dr. Cipto Mangunkusumo National General Hospital (RSCM), Jakarta, Indonesia

Participants: Children with cerebral palsy attending the Pediatric Outpatient Clinic of Physical Medicine and Rehabilitation at RSCM during the study period were screened for eligibility.

- Inclusion criteria:
    - Children diagnosed with Spastic Quadriplegic Cerebral Palsy by a pediatrician or pediatric neurologist
    - Modified Ashworth Scale (MAS) score of ≥1+ at the gastrocnemius muscle
    - No fixed contracture of the affected skeletal muscles
    - Parents or legal guardians who provided written informed consent after receiving education about the fESWT and rESWT procedures and their associated risks
- Exclusion criteria:
    - Parents or caregivers who are unable to cooperate during clinical assessments
    - Parents or caregivers who are unwilling to participate in the study
    - Children who are acutely ill at the time of intervention (e.g., with cough, fever, or upper respiratory tract infection)
    - Children who had received botulinum toxin type A injection within the past 6 months
    - Children who had undergone lower limb surgery within the past 12 months

Randomization

Participants will be recruited consecutively from the outpatient clinic on a first-come, first-served basis. Following confirmation of eligibility, participants will be randomly allocated to either the fESWT group (Group A) or the rESWT group (Group B) using a computer-generated random number sequence. Each participant will contribute both gastrocnemius muscles to their allocated group, resulting in two gastrocnemius samples per child to be included in the analysis.

Intervention

Both groups will receive ESWT by trained clinicians using a single device platform according to group allocation. Dosing parameters were kept identical across the two groups:

- Total impulses per session: 1,500 shocks
- Pressure: 2 bar
- Frequency: 6 Hz
- Energy intensity: medium
- Treatment frequency: once weekly for four consecutive weeks (Weeks 1–4)
- Treatment area: gastrocnemius muscle bellies, including both medial and lateral heads, applied using a sweeping technique from the gastrocnemius down to the soleus
- Coupling medium: standard ultrasound gel
- Patient position: prone with the knee extended and the ankle in the patient's comfortable position

Treatment will be discontinued at the discretion of the treating clinician in the event of acute illness, skin irritation at the treatment site, or other clinical concerns. Adverse effects will be monitored at each treatment session and follow-up visit.

Outcome Measure

The primary outcome is the Modified Ashworth Scale (MAS) score of the gastrocnemius muscle, will be recorded as an ordinal score on a 6-point scale (0, 1, 1.5, 2, 3, and 4), measuring resistance to passive stretch.

Assessment Time Points

All outcome measures are assessed by the blinded outcome assessor at the following time points:

- T0 (Pre-intervention) — Baseline, prior to the first ESWT session
- T1 (Post-intervention week 1) — Following the first weekly ESWT session
- T2 (Post-intervention week 2) — Following the second weekly ESWT session
- T3 (Post-intervention week 3) — Following the first weekly ESWT session
- T4 (Post-intervention week 4) — Following the fourth weekly ESWT session (end of therapy phase)
- EV1 (Evaluation 1) — Month 2 follow-up (4 weeks after T4)
- EV2 (Evaluation 2) — Month 3 follow-up (8 weeks after T4)
- EV3 (Evaluation 3) — Month 4 follow-up (12 weeks after T4)

Statistical Analysis Plan

Software and Significance Threshold: Statistical analyses will be performed using SPSS version 26.0. Statistical significance was set at $p < 0.05$.

Data Presentation: MAS scores will be expressed as medians with interquartile ranges (IQR).

Between-Group Comparisons: Fisher's exact test will be used to compare the proportion of MAS score categories (MAS < 2 and MAS ≥ 2) between the fESWT and rESWT groups at all time points. Between-group comparisons of MAS scores at each time point will be evaluated using the Mann-Whitney U test.

Within-Group Comparisons: Within-group changes over time will be evaluated using the Wilcoxon signed-rank test to compare pre-intervention with post-intervention weeks 1, 2, 3, 4, and evaluation 3. Additionally, changes from post-intervention week 4 will be compared across subsequent follow-up evaluations (evaluation 1, 2, and 3).

Subgroup Analyses: Wilcoxon signed-rank test will also used for subgroup within-group comparisons in participants with baseline MAS < 2 and MAS ≥ 2.