Official title: the Investigation of Therapeutic Effect After ILIB for Ischemic Stroke Patient

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Study Protocol with SAP

objective(s): Stroke is a leading cause of disability worldwide. ILIB therapy has been reported to improve circulation, reduce blood viscosity, and modulate immune responses, but robust evidence in ischemic stroke is lacking. Therefore, the aim of this study is to evaluate the clinical efficacy of intravenous laser irradiation of blood (ILIB) therapy as an adjunct treatment for patients with ischemic stroke.

methods: This study was designed as a double-blind randomized controlled trial, with ethical approval obtained from the appropriate institutional review board of Tri-Service General Hospital, Taipei, Taiwan (No. A202105058). The participants were randomly assigned in a 1:1 ratio to the ILIB or control group using a computer-generated randomized number. Participants assigned to the ILIB group underwent intravenous helium-neon laser therapy at a wavelength of 632.8 nm (Classconn helium-neon Laser System, Medipark, Korea). A peripheral vein in the antecubital fossa was cannulated by using an indwelling needle, allowing for the insertion of a laser fiber catheter. The ILIB power was set between 2.5 mW and 3.0 mW, performed 60 min/session, energy 9 – 10.8 J/session, once daily for 5 consecutive days per week for 2 weeks, with a total of 10 interventions. The control group received the same intervention but without the output power. All participants received physical therapy and activities of daily living training for one hour each time, three times a week during the study period. The following outcome measures were assessed at baseline and at 3 days, 1 month, and 3 months post intervention: National Institute of Health Stroke Scale score, modified Rankin Scale (mRS) score, Stroke Impact Scale (SIS) score, Fugl-Meyer assessment-Motor Function (FMA-MF) score, and 6-minute walking test (6MWT) performance.

statistical analysis plan: The sample size calculation was performed using STATA software (Power analysis for a two-sample means test), with a significance level of $\alpha = 0.05$ and power $(1–\beta) = 0.80$. The effect size are calculated by control (39.2±17.5) and experiment (20.9±8.4). The required sample size was estimated to be 22 participants. The final analyzed sample (n = 22) met the minimum requirement for analysis. The Mann-Whitney U, Chi-square, or Fisher's exact tests were used to analyze continuous and categorical data. Intergroup comparisons of mean differences across different time points were conducted using the independent t-test or Mann-Whitney U test. Meanwhile, intragroup comparisons of baseline data were performed using Wilcoxon signed-rank tests. All statistical analyses were conducted using SPSS Statistics, Version 22 (IBM Corp., Armonk, NY, USA), with a significance level set at $P < 0.05$.