Statistical Analysis Plan (SAP)

Study Title: Effectiveness of rTMS on Pain and Quality of Life in Patients With Cancer Neuropathic Pain

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1. Objectives of the Statistical Analysis

The primary objective of the statistical analysis is to assess the effectiveness of transcranial magnetic stimulation (TMS) in reducing oncological neuropathic pain and improving quality of life in patients with cancer. This includes analyzing changes in Visual Analogue Scale (VAS), Brief Pain Inventory (BPI), and quality of life indicators (FACT-G and NTX subscales).

2. General Considerations

- All analyses will be conducted using IBM SPSS Statistics software (version specified in final results).
- A p-value < 0.05 will be considered statistically significant.
- No data imputation will be performed; all analyses will be based on observed values (complete case analysis).
- Assumptions required for each test (e.g., normality) will be tested and reported.

3. Descriptive Analyses

- Continuous variables (e.g., age, VAS scores, BPI scores) will be described using means, standard deviations, medians, ranges, and percentiles, depending on the distribution of the data.
- Categorical variables (e.g., sex) will be reported as frequencies and percentages.

4. Assessment of Normality

- The normality of continuous outcome variables will be tested using the **Shapiro-Wilk test**.
- If variables are not normally distributed, non-parametric methods will be used for inferential comparisons.

5. Inferential Analyses

5.1. Within-Subject Comparisons

To evaluate the effectiveness of TMS over time:

- **Wilcoxon signed-rank test** will be used for paired comparisons of non-parametric variables between baseline and subsequent time points (e.g., Pre-VAS vs Day 5, Day 10, etc.).
- **Paired t-tests** will be used only if variables demonstrate normal distribution.

5.2. Repeated Measures Analysis

- **Repeated measures ANOVA** will be conducted to evaluate the impact of the intervention over multiple time points for continuous outcome variables such as VAS, FACT-G, and TOI.
- When the sphericity assumption is violated (tested via **Mauchly's test**), Greenhouse-Geisser or Huynh-Feldt corrections will be applied.
- **Effect sizes (partial eta squared)** and **observed power** will be reported for all significant outcomes.

6. Multivariable Analysis

- If sample size allows, analysis of covariance (ANCOVA) or linear mixed models may be considered to adjust for potential confounders such as age, sex, and baseline pain level.

7. Handling of Multiple Comparisons

- Due to the exploratory nature of the study and small sample size, no formal adjustment for multiple comparisons will be applied. However, results will be interpreted with caution, and this limitation will be noted in the final report.

8. Subgroup Analyses

- No pre-specified subgroup analyses are planned due to limited sample size.

9. Deviations from Planned Analysis

- Any deviations from this pre-specified plan will be documented and justified in the final study report.