

STATISTICAL ANALYSIS PLAN (SAP)

Study: Levetiracetam Versus Phenobarbitone for the Treatment of Neonatal Seizures in a
Tertiary Care Hospital

Principal Investigator: Dr. Gohar Ali

Official Study Title:

**Levetiracetam Versus Phenobarbitone for the Treatment of Neonatal Seizures in a
Tertiary Care Hospital**

Short title/acronyms: **Levetiracetam Versus Phenobarbitone for the Treatment of Neonatal
Seizures**

ClinicalTrials.gov Identifier:

NCT Not Yet Assigned

Organization's Unique Protocol ID:

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Document Type:

Statistical Analysis Plan (SAP)

Date:

Study Start Date

April 08 2024

Primary Completion Date

March 31 2025

Study Completion Date

April 10 2025

Prepared By:

Dr. Gohar Ali

Analysis Population

- **All randomized neonates** (Intention-to-Treat, ITT)
- **Per-protocol population** for sensitivity analysis (neonates who completed treatment as per protocol)

Descriptive Statistics

- **Continuous variables:** mean \pm SD or median (IQR)
- **Categorical variables:** frequency (%)

Outcome Analysis

Primary Outcome:

- Seizure control rate within 24 hours
 - **Compare** seizure control between levetiracetam and phenobarbitone groups
 - **Statistical Test:** Chi-square or Fisher's exact test
 - **Significance level:** $\alpha = 0.05$

Secondary Outcome Analysis

- **Time to seizure cessation**
 - Independent t-test or Mann–Whitney U test
- **Need for second-line anticonvulsant**
 - Chi-square test
- **Seizure recurrence during hospital stay**
 - Chi-square test
- **Adverse drug reactions**
 - Chi-square test
- **Mortality during hospital stay**
 - Chi-square test

Subgroup Analysis (optional)

- Preterm vs Term neonates
- Birth weight <2500 g vs ≥ 2500 g
- Etiology of seizures (HIE vs metabolic vs infection vs others)

Handling Missing Data

- **Multiple imputation** if missing data $> 5\%$
- **Sensitivity analysis** comparing complete case vs imputed dataset

Software

- Analysis performed using **SPSS version 23**,

Reporting

- **Two-sided p-values**
- **95% confidence intervals** for effect estimates
- **Tables and figures** for primary and secondary outcomes