

Cerebroprotective Effect of Melatonin in Acute Ischemic Stroke

Document date: december 7th 2022

Statistical Analysis

The primary outcome of this study will be clinical outcome, and secondary outcomes will include the effects of the treatment on anti-inflammatory, antioxidant, antiapoptotic, endothelial injury, and infarct volume. Patients will be stratified according to the treatment received, and descriptive analysis will be carried out. Categorical variables will be presented in frequencies and efficacy will be assessed by calculating the magnitude of association with chi-square between the analyzed outcome and drug intake, obtaining RR and CI. Non-parametric ANOVA will be used to evaluate differences.

To assess safety, percentages of adverse events will be obtained and Fisher exact test will be performed, obtaining RR and CI. Continuous variables will be presented as medians, and Kolmogorov-Smirnov test will be used to assess normality. For quantitative variables (biomarkers and infarct volume), parametric methods will be used to obtain means, CI, and standard deviation, and for non-parametric data, medians with interquartile ranges and percentages will be calculated when indicated. Intragroup differences at each point of time will be carried out using ANOVA of repeated measures with post-hoc test through Wilcoxon or Tukey. For intergroup differences, ANOVA of one way will be used. A multivariate logistic regression will be performed to estimate the relationship between clinical outcome and biomarkers, as well as infarct volume.

The correlation between variables will be demonstrated with Pearson or Spearman as appropriate. Statistically, significant differences will be considered with a p-value of less than 0.05. The statistical package SPSS v23.0.0.2, GraphPrism 6.0, and Microsoft Excel 15.32 will be used for the analysis.