



**Title: Efficacy, Safety and Tolerability of
Ivermectin in Subjects Infected With SARS-
CoV-2 With or Without Symptoms
“SILVER BULLET”**

NCT04407507

Date: august 5, 2020

Statistical Analysis Plan

1. Data analysis

1.1 Statistical considerations

The data will be presented with measures of central tendency and dispersion: mean and standard deviation. For ordinal quantitative variables, they will be presented in frequencies and percentages.

The statistical analysis to find differences between the groups will be carried out by means of the T test, and for ordinal variables it will be calculated by means of Chi2.

To find a relationship between two variables, a Pearson correlation will be used, and for a relationship analysis of several variables, a linear regression model will be used.

All analyzes will be carried out for the entire study population. When possible, the data will be stratified by subgroups.

Values of $p < 0.05$ will be considered significant at all times.

Tables and graphs will be made as deemed most pertinent.

The SPSS statistical package, version 19 will be used.

1.2 Additional analysis

They will be carried out according to what the IP considers, if required.

1.3 Population analysis and management of missing data

For the statistical analysis, all those subjects who, at least, complete two visits will be considered. However, an intention-to-treat analysis will be performed if deemed appropriate. Those subjects who do not have data will not be replaced by others.

1.4 Exploratory analysis

An exploratory analysis will be performed to identify the nature of the variables and their distribution. For the quantitative variables, Kolmogorov-Smirnov tests will be carried out to identify if they conform to the assumptions of normality. If this happens, the results will be displayed in tables and graphs as means and standard deviations, and categorical data will be displayed as proportions with their corresponding 95% confidence intervals.

1.5 Demographic analysis, disease details, previous medications, and other baseline information.

The baseline characteristics of the patients will be summarized using means (SD) for continuous variables and frequencies (percentage) for categorical variables. Baseline characteristics will be compared between treatment groups using standardized differences. Baseline characteristics with a standardized difference <10% will be considered balanced.

1.6 Analysis of the primary endpoints

The frequency of subjects with mild to severe disease progression, will be evaluated between groups using the Chi2 test.

1.7 Analysis of secondary evaluation variables

- The replication rate of the SARS-CoV-2 virus will be evaluated by means of the day between day 5 and day -2 (selection), between day 14-day 5, and day 14-day-2, the means of the will be compared with a student's T-sample.
- The symptoms, adverse events, the presence of comorbidities and the medical history of BCG will be measured in frequencies and will be evaluated with the Chi2 test.
- The analysis of the numerical variables (viral replication, number of symptoms, weights and laboratory tests) will be carried out, in addition to comparing means with the t-student test, with Pearson's correlation and with linear regression models.

1.8 Analysis of adverse events

Analysis of adverse events will be performed in all patients who have received at least one dose of ivermectin. For the description of adverse events, a frequency table will be made. The analysis will be carried out like that of the secondary endpoints.

CONFIDENTIAL