STATISTICAL ANALYSIS PLAN (SAP)

Project Title

A multicenter, single blind, randomized controlled trial of virucidal effect of Polyvinylpyrrolidone-Iodine on SARS-CoV-2 as well as safety of its application on nasopharynx & oropharynx of COVID-19 positive patients

BMRC Reg. No: 38624012021

Statistical Analysis Plan (SAP)

1. Sampling Technique

Sample Size

- The minimum sample size is given by:

Where, n= sample size ,Z = Standard normal deviate usually set at 1.96 at 95% confidence If prevalence is not known, the value of prevalence will be considered as 50%.

So, p will be 0.5.

So, q = (1-p) = 0.50, and

d = Desired accuracy or degree of allowable error. It is usually set as 5%(0.05).

So, $n = \{(1.96)^2 \times 0.5 \times 0.5\} / (0.05)^2$

Or, n = 384

for a finite population $n = (Z^2 \times p \times q) / d^2$

N.B. Calculated sample size is equally applicable for both experimental (Intervention) and control group.

2. Statistical Analysis tools

Data analysis software	: Statistical Package for the Social Sciences (SPSS)
Descriptive statistical parameter	: Mean, Medium, Mode, Standard Deviation, Percentage, Frequency
Inferential statistics	: Chi-square test, t-tes, F-test, Anova, Correlation
Confidence Interval	: 95%