Single-used versus MultiPlE-used endotracheal suCtIon cAtheters in mechanically ventiLated ICU patients: the SPECIAL-ICU trial

Short title: SPECIAL-ICU trial

Statistical Analysis Plan, Version 1

Dated 14th of December 2023

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1 STATISTICAL ANALYSIS CONSIDERATIONS

1.1 Sample Size

As a feasibility RCT, no formal power calculation will be undertaken (Eldridge et al. 2016). One of the aims of the study is to select the most appropriate primary and secondary outcome measures and inform the sample size for calculation of the future RCT. There is no consensus on the feasibility study recommended number of participants, suggested numbers ranging from 20 -70 (Whitehead et al., 2016). Therefore, this feasibility study aims to recruit 60 participants.

1.2 Statistical Analysis

Participants will be recruited for a minimum of three days and a maximum of eight days. The planned recruitment period is three-six months. Participants initial evaluation will be on the 3rd day of ICU admission and the second one will be on the 6th day. The follow-up rate is estimated to be 50% or more. An extended CONSORT flow diagram will be used to present descriptive data on screening, enrolment, intervention allocation, and follow-up. It will also show any deviations from protocol, for example, participants developed any unexpected side effects. The modified CPIS will be calculated for each study participant within each study group to compare VAP incidence in each group which will be represented through cross tables and figures. Other descriptive data findings will be also represented through tables/figures.

Data will be presented as frequency and percentages (qualitative variables) and mean ± SD (quantitative continuous variables). Chi-square (x2) will be used for comparison of categorical variables and will be replaced by Fisher exact test (FET) or Mont Carlo Exact test if the expected value of any cell is less than 5. The student's t-test will be used for the comparison of continuous quantitative variables. For continuous quantitative variables that will not normally distributed, Median will be used as a central tendency measure. The Mann Whitney test (Z) will be used to compare the three groups. The difference will be considered significant at $P \leq 0.05$. Statistical advised will be sought.

1.3 Analysis populations

All analyses and data summaries will be conducted on the intention-to-treat (ITT) population which is defined as all enrolled participants and followed up at least for 3 days in ICU, and also critical care

nurses who conducted the study. Withdrawn Patients and critical care nurses who will refuse to be interviewed will not be included in the analysis.

1.4 Frequency of analysis

There is no planned interim analysis. Statistical analysis will be undertaken after the last participant's follow up.

1.5 Outcome analysis

As a feasibility study, analysis will focus on descriptive statistics and confidence interval (CI) estimation rather than formal hypothesis testing.

1.6 Primary analysis

The aim of this primary analysis is to assess the feasibility of delivering the intervention in the study settings, and selection of primary and secondary outcome measures. Components to be analysed are:

feasibility of a trial by producing:

- CONSORT diagram
- Timing of follow-up assessments
- Time it took to recruit participants
- Number of critical care nurses willing to participate
- Randomization technique effectiveness

feasibility of the intervention by producing:

- Critical care nurses' acceptability of the intervention
- Method of delivering the intervention to each study arm

Selection of primary/secondary outcomes

- comparing outcomes of each study group