

Statistical Analysis Plan

Use of abdominal binder in colonoscopies performed by trainees in
Gastrointestinal Endoscopy: A randomized, double-blind, sham-
controlled trial

NCT05617521

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Sample size was estimated over the primary outcome of the study based on pre-experimental data estimation and previously reported CIT and SD of similar studies with fellows' participation. It was calculated that 142 participants were needed to detect a 60-second difference in CIT (SD 110 sec), with 90% power and two-side alpha 0.05. Moreover, it was also calculated based on the frequency of ancillary maneuvers, using pre-experimental data estimation and literature data. It was found that 186 participants (93 per group) were needed to detect a 20% reduction in the use of ancillary maneuvers, with 90% power and two-side alpha 0.05. As a preventive measure in case of withdrawal or exclusion, the sample was expanded by 10%, a total of 206 patients, 103 in each group were included in the study.

Descriptive statistical analysis, including mean, mode, and frequencies will be performed for the description of the study data. The comparative analysis of the quantitative data will be previously subjected to normality evaluation by the Shapiro–Wilk test and graphical analyses. According to the normality, data comparative analysis will be performed either with a two-way Student's test or U Mann–Whitney test. For the comparative analyses of the categorical data (e.g., manual abdominal compression, postural change, need of intervention by the attending endoscopist) will be used chi-square or Fisher' exact test. A p value of <0.05 will be accepted as statistical significance. Statistical inferential analysis will be performed using RStudio® (R Core Team v.1.2.5033; R Foundation for Statistical Computing, Vienna, Austria) and SPSS® Statistics for Windows Version 23.0 (IBM Corp., Armonk, NY, USA). RStudio® (R Core Team v.1.2.5033) will be also used for drawing graphics. The study biostatistician (SA) will be blinded to the randomization phase and recollection data process.