Statistical design

Sample size calculation

Currently, there is no comparative study between Absolok and Hem-o-lok clips in terms of perioperative bleeding in colorectal surgery. Therefore, this study is configured as a pilot study, such that a formal calculation of the sample size is not necessary. Thus, all patients undergoing colorectal surgery at the Ospedale Isola Tiberina – Gemelli Isola of Rome will be enrolled in the study. Enrollment will last 1 year (12 months) from the start date of the study. Eligible participants were randomized 1:1 to Absolok® or Hem-o-Lok® using a computer-generated allocation sequence (PASS 2019) without stratification. According to mean number of colorectal resections performed during the previous two years, a total number of almost 200 patients are expected to be enrolled.

Statistical analysis

All variables will be represented by descriptive statistics techniques. In depth, data will be reported as absolute and percentage frequencies, as for qualitative variables. Quantitative data distribution will be assessed using the Shapiro-Wilk test. Hence, data will be expressed either as mean ± standard deviation (SD) or median and interquartile range (IQR), as appropriate.

As for the primary endpoint, the difference between Absolok and Hem-o-lok in terms of achievement rate of Grade ≤3 hemostasis for each vessel clipped and transected (dichotomous variable) will be assessed by the Fisher exact test. The single grading scale will be further reported.

Between groups differences will be assessed by the Fisher exact test and the Chi-square test, with Yates correction, as appropriate, in the case of qualitative variables. Quantitative data, indeed, will be assessed either by the Student’s t test or the non-parametric Mann Whitney U test, as appropriate.

As for the secondary endpoints, the potential association between the type of clip employed and the intraoperative and postoperative courses will be computed by using the same test, as aforementioned.

All analyses will be performed by using R software, version 4.1.2 (CRAN ®, R Core 2020).