COVER PAGE

Statistical Analysis Plan

BBK 3 - study

Randomised comparison of Culotte technique versus "Double Kissing" – Crush technique (DK-Crush) for the percutaneous treatment of de novo non-left main coronary bifurcation lesions with modern everolimus-eluting stents (DES) – European multicenter study

December 09th 2019

Statistical Analysis Plan

A modified intention-to-treat analysis of angiographic outcome measures will be performed, including the primary endpoint, which is restricted to patients with follow-up angiography.

Clinical endpoints will be analyzed according to the intention-to-treat principle. For all statistical analyses, we will use the current version of the SPSS software package. Discrete variables were reported as counts (percentages) and continuous variables as mean +/- standard deviation.

For discrete variables, we will test differences between groups with the chi-square test or Fisher exact test when expected cell sizes are less than five.

Two-tailed t-tests will be used to compare continuous variables. As a sensitivity analysis, we will also perform analysis of covariance with pertinent baseline variables as covariates, to corroborate our primary analysis. All tests are two-sided and statistically significance is considered at 5%.