Statistical Analysis Plan (SAP)

Study Title: Use of Various Types of Introducers in Conventional Radial Access (TIRE)

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1. Introduction

This Statistical Analysis Plan (SAP) describes the pre-specified statistical methods and procedures that will be used to analyze data for the clinical trial entitled «Use of Various Types of Introducers in Conventional Radial Access (TIRE)».

2. Study Objective

To compare different types of radial introducers used in conventional radial access by the frequency of complications in routine clinical practice.

3. Outcome Measures

- compare the frequency of occurrence EASY Grade II hematoma between groups (Rad classic vs Rad polymer vs Rad slender);
- compare the frequency of occurrence acute radial artery occlusion between groups (Rad classic vs Rad polymer vs Rad slender);
- compare the frequency of occurrence radial artery perforation between groups (Rad classic vs Rad polymer vs Rad slender);
- compare the frequency of occurrence radial artery false aneurysm between groups (Rad classic vs Rad polymer vs Rad slender);
- compare the frequency of occurrence persistent radial artery spasm between groups (Rad classic vs Rad polymer vs Rad slender);
- compare the frequency of occurrence total frequency of major complications between groups (Rad classic vs Rad polymer vs Rad slender).

4. Determining Sample Size and Randomization Methods

The required sample size was calculated using the method of M. Bland for a high-precision study. The required significance level (α) was 0.001 and the statistical power was 95%. The expected rate of radial artery occlusion in the Rad, Rad polymer, and Rad slender groups was assumed to be 12%, 8%, and 8%, respectively. Under these conditions, the calculated sample size was 2723 patients. The planned loss during the study was 20%. Thus, the minimum sample size was 3268 patients.

The study had an experimental design and complied with the CONSORT protocol. A simple randomization method using a random-number generator was chosen. The type of randomization was permuted block randomization. The total block size was 3000, and the allocation ratio between the groups was 1:1:0.7.

5. Statistical Methods

Results are presented as median with interquartile range (25th and 75th percentiles) or as number of cases and percentage. The Mann-Whitney U test was used to compare quantitative data. Yates-corrected chi-square was used to compare qualitative variables. To assess the effect of a specific factor, relative risk (RR) with 95% confidence interval (95% CI) was also calculated. Differences between groups were considered significant at $p < 0.05$. When a significant difference was obtained between indicators, the NNT index (number needed to treat to prevent 1 adverse event) was additionally calculated.

6. Interim Analyses

No interim analyses are planned for this study.

7. Software

Statistical analysis of the results was performed using Statistica version 13.3 (TIBCO Software Inc., 2017).

8. Approval

This SAP was finalized and approved prior to database lock and commencement of statistical analyses.