Study identification

Official Title: Safety and Effectiveness of Drug up Titration by Nurses Specialized in Heart Failure (HF) Patients.

ClinicalTrials.gov Identifier: *NCT02546856.*

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Statistical Analysis

The analysis was performed on an intention-to-treat basis. Both the Student's t-test (or the non-parametric Wilcoxon test if continuous data are not normally distributed) and the chi-squared test (or Fisher's exact test) were used to compare the baseline socio-demographic and clinical characteristics of patients in the two groups. The effect attributable to the intervention was estimated by comparing the differences in the relative dose of BB (primary end-point of the study), ACEI, ARB and MRA reached between the groups, assessed at 4 months after starting titration, and the 95% confidence interval was calculated.

All variables with a p value <0.20 were included as explanatory variables in a multivariate model, with relative dose as the response variable. The effect of time was estimated in two repeated measurements for each subject, using mixed linear regression models with fixed effects (time, intervention, interaction between time and intervention) and random effects (specific effect of each subject and centre at the reference level and the effect of time). These models took into account the longitudinal structure of the two repeated measurements, as well as the hierarchical and multicentric structure of the data. All the statistical analyses were performed, using SAS System v 9.4, with statistical significance set at $p<0.05$.