Statistical analysis plan

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Brief Summary

The study aims to validate naevia medical, a knowledge-based clinical decision support system (CDSS), for clinical benefit and safety in cases of cardiac valvulopathies. Using a series of retrospective clinical cases of heart valve disease, the research will evaluate the number of appropriate and inappropriate recommendations during baseline measurement (conventional management) and after CDSS activation.

Statistical analysis plan

The study is designed as a pre-test-post-test evaluation of a randomly assigned group, using a longitudinal repeated measures approach and retrospective validation. The clinical management of the included cases will be retrospectively evaluated by a panel of 3 experts with access to the most updated guidelines. For each case, the panel will perform the assessment at baseline (without CDSS) and repeated the assessment after the activation of the CDSS. The experts will label all the given clinical recommendations as appropriate or inappropriate and will identify the ones that are missing but relevant for clinical decision making. Finally, they will state their grade of agreement with the CDSS suggestions on a five-level Likert scale. The number and percentage of appropriate, inappropriate and missing relevant recommendations in each scenario will be considered for analysis.

Analysis of the amount and quality of recommendations

The impact of the CDSS activation on the recommendations will be assessed by analyzing the *number* of recommendations (appropriate, inappropriate, missing) per patient. The mean number of appropriate, inappropriate, and missing relevant recommendations generated per patient will be compared before and after the CDSS activation. Descriptive statistics, including mean (standard deviation [SD]), median (interquartile range [IQR]), and range, will be reported for these counts. To statistically compare the distributions of the *number* of appropriate, inappropriate, and missing recommendations per patient before and after CDSS implementation, the Wilcoxon signed-rank test will be applied.