AMENDMENT OF THE

TRIAL STATISTICAL ANALYSIS PLAN

PERI-INTERVENTIONAL OUTCOME STUDY IN THE ELDERLY (POSE):

EUROPEAN, MULTI-CENTRE, PROSPECTIVE OBSERVATIONAL

COHORT STUDY

AMENDMENT OF VERSION 1.0, 10.10.2019

NEW VERSION IS VERSION 1.1, 20.01.2020

Clinical Trials.gov	NCT03152734
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1. DESCRIPTION AND RATIONALE OF THE AMENDMENTS

1.1 SENSITIVITY ANALYSES

The sensitivity analysis of the primary endpoint (time until all-cause mortality) with a follow up period that is not limited to 30 days was dismissed because the data was systematically collected only up to day 30 according to the study protocol.

In order to consider the possible interaction between different independent variables, a sensitivity analysis of the primary endpoint (time until all-cause mortality) with interaction effects was added. The following 2-way interactions were included: Age and premedication before intervention, Frailty and premedication, Anaesthesia technique and severity of intervention. The interaction effects were chosen based on clinical relevance.

1.2 MINOR CHANGES

Minor changes include the correction of typos and the addition of explanatory comments:

- 5.3 SENSITIVITY ANALYSES: The description of the sensitivity analysis without multiple imputation was adjusted in order to clarify that the independent variables are the same as in the main analysis.
- 8.1 PRIMARY ENDPOINT: The description of the variable selection technique of the multivariable Cox model has been slightly adapted so that it is also applicable to variables without missing data.
- 8.1 PRIMARY ENDPOINT: The description for checking the Schoenfeld residuals has been slightly adapted so that it is also applicable to variables without missing data.
- 8.1 PRIMARY ENDPOINT: Some errors in the SAS code were corrected (the random center effect was incorrectly typed as Sex, the imputation variable name was missing an underscore, and minor typos were corrected).