

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 1.1, 20.01.2010

NEW VERSION IS VERSION 1.2, 11.02.2020

Clinical Trials.gov	NCT03152734
Chief Coordinating Investigator	Prof. Dr. Mark Coburn, MD Managing Senior Physician Department of Anaesthesia Medical Faculty, RWTH Aachen University, Germany
Biostatistician	Prof. Dr. Ralf-Dieter Hilgers, PhD Head of the Department of Medical Statistics Medical Faculty, RWTH Aachen University, Germany Marcia Viviane Rückbeil, M. Sc. Department of Medical Statistics Medical Faculty, RWTH Aachen University, Germany
Central Organisation/ Project Management	Dr. Ana Kowark (née Stevanovic), MD Department of Anaesthesia Medical Faculty, RWTH Aachen University, Germany

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1. DESCRIPTION AND RATIONALE OF THE AMENDMENTS

1.1 DEFINITION OF INDEPENDENT VARIABLES

The comorbidity ‘hypertension requiring medication’ at baseline was added to the list of comorbidities considered. This affects the criterion of at least 3 comorbidities as part of the frailty definition (6.7.1) and the definition of multimorbidity (6.7.2).

1.2 MINOR CHANGES

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

- 5.2 SECONDARY ENDPOINTS: The description of the outcome ‘Any complications after discharge’ has been adapted to clarify that only cardiac, pulmonary, stroke, and AKI complications are considered.