Protocol for MAAESTRO: Electronic Monitoring and Improvement of Adherence to Direct Oral Anticoagulant Treatment-A Randomized Crossover Study of an Educational and Reminder-Based Intervention in Ischemic Stroke Patients Under Polypharmacy

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Background: Non-adherence to direct oral anticoagulants (DOACs) remains a matter of concern, especially for patients with a recent stroke. However, data on electronically monitored adherence and adherence-improving interventions are scarce. Aims: We aim to use electronic monitoring in DOAC-treated stroke patients to (i) evaluate the effect of an educational, reminder-based adherence-improving intervention, (ii) investigate predictors of non-adherence, (iii) identify reliable self-report measures of adherence, and (iv) explore the association of non-adherence with clinical outcomes. Methods: Single-center, randomized, crossover, open-label study. Adherence to DOACs of polymedicated patients self-administering their medication will be monitored electronically throughout the 12-month-long study following hospitalization for ischemic stroke. After a 6-month observational phase, patients will receive pharmaceutical counseling with feedback on their intake history and be given a multi-compartment pillbox for the subsequent 6-month interventional phase. The pillbox will provide intake reminders either during the first or the last three interventional-phase months. Patients will be randomly allocated to reminders-first or reminders-last. Study outcomes: Primary: non-optimal timing adherence; Secondary: non-optimal taking adherence; timing adherence; taking adherence; self-reported adherence; clinical outcomes including ischemic and hemorrhagic events; patient-reported device usability and satisfaction. Sample size estimates: A sample of 130 patients provides 90% power to show a 20% improvement of the primary adherence outcome with intake reminders. Discussion: MAAESTRO will investigate various aspects of non-adherence and evaluate the effect of an adherence-improving intervention in DOAC-treated patients with a recent stroke using electronic monitoring. Clinical Trial Registration: ClinicalTrials.gov identifier: NCT03344146, Swiss National Clinical Trials Portal SNCTP000002410.
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