Standardization of the definition of clinical outcome for patients treated for a major oral anticoagulant related bleed

Control of Anticoagulation

Person responsible (Chair / Principal Investigator): Nakisa Khorsand

Description Abstract

In 2016, on behalf of the Scientific and Standardization Subcommittee (SSC) on Control of Anticoagulation of the International Society on Thrombosis and Haemostasis (ISTH), we proposed criteria to evaluate the effectiveness of anticoagulant reversal in major bleeding management. Testing and validation of these criteria is required.

To validate our recommendation for the definition of clinical outcome in patients treated for a major oral anticoagulant (VKA & NOAC) related bleed.

Design and methodology (Data expected to collect, sample size and statistical analysis):

To validate the formulated recommendation, patient data from three anticoagulant-antidote studies will be used. For these patients haemostatic effectiveness will be assessed using the ISTH proposed definitions and using clinical opinion by four adjudicators.

Study population (Inclusion, exclusion, eligibility) (patient population; recruitment of participating institutions/physicians and subjects; minimum number needed; expected number):

patient data from three anticoagulant-antidote studies or registries that the project team have access to will be used.
SSC Subcommittee Project/Collaborative Project

Expected timeline:

- Project stage/set up
  - Launch: 2014 (formulation), 2016 (validation)
  - Duration: End of 2015 (SSC communication was published in JTH). End of 2019 (validation)
  - Finalization/analysis: 2019
  - Reporting: SSC communication

Expected outcomes (ie. publications):

- Original article (validation of the endpoints)
- SSC Communication (standardization of the definition- suggested revision after validation)

Description of project set/up and management, needed infrastructure and resources (summary):

**Project team:** Rahat Abdoellakhan, Sam Schulman, Jan Beyer-Westendorf, Ravi Sarode, Karina Meijer, Nakisa Khorsand

**References:**