

Research Project

BASEL IX (BAseL Syncope EvaLuation Study): Validation

Third-party funded project

Project title BASEL IX (BAseL Syncope EvaLuation Study): Validation

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Organisation / Research unit

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Department

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Status Completed

Syncope is frequent and represents 1-2% of all Emergency Department (ED) visits. The ED-evaluation of patients with syncope is challenging, generally time and resource consuming. In the first phase of BASEL IX, which was mainly conducted in EDs in Switzerland, several important insights and novel diagnostic algorithms emerged. However, numerous important questions remain regarding these algorithms, particularly the need to be validated in a large prospective validation cohort before they can be recommended for widespread clinical use. Aims: The aim of the current application is to extend the work in the ongoing and highly successful BASEL IX (BAseL Syncope EvaLuation Study) in order to test the generalizability of the initial findings and to provide additional insights for diagnosis and risk stratification. Methodology: BASEL IX is a large ongoing prospective international diagnostic study enrolling unselected patients presenting with syncope to the ED in thirteen hospitals in eight countries on three continents. It is conducted by a dynamic network of academic, clinical and industry collaborators experienced in the field of syncope and cardiac biomarkers. In the new application period (BASEL IX Validation) we will enroll 2'000 additional patients. It is our primary objective to validate the diagnostic performance of the recently developed algorithm implementing the combination of a low ED-probability and a low plasma level of midregional pro A-type natriuretic peptide (MRproANP) against a gold standard diagnosis adjudicated centrally by two independent cardiologists according to the latest European Society of Cardiology (ESC) guidelines using all information becoming available during clinical work-up including 1-year follow-up. Secondary objectives include the evaluation of a) age-, circadian, and sex-optimized cut-off levels for MR-proANP and ED clinical judgment to derivate and validate personalized diagnostic algorithms b) other biochemical signatures including other natriuretic peptides (e.g. B-type natriuretic peptide and NT-proBNP) c) electrocardiographic signatures to improve the early diagnosis of cardiac syncope. As the main causes of cardiac syncope are arrhythmic disorders, ECG-signals may provide incremental value in diagnosing cardiac syncope. The latter includes the attempt to incorporate an ECG-marker into our algorithm combining clinical judgement and a cardiac biomarker to further improve its accuracy, efficacy and safety d) the prevalence of pulmonary embolism as the cause of syncope among patients presenting to the ED and e) the best clinical use of implantable loop recorders in the management of patients with unexplained syncope. Potential significance: This study will provide insights that will contribute to improvements in diagnosis and risk stratification of cardiac syncope and will therefore have important clinical and economic implications on patient management in Switzerland and worldwide.

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