BEISPIELSTUDIE

Elderly patients with venous thromboembolism (SWITCO65+): a longitudinal study of the Swiss Cohort

KATEGORISIERUNG

Gattung
Forschungsprojekt mit lebenden Personen

Art
Nicht als klinischer Versuch geltendes Forschungsprojekt (i.d.R. Beobachtungsstudie)

Unterart

BACKGROUND

Venous thromboembolism is common and significantly increases morbidity, mortality, and costs of care. Although most patients with venous thromboembolism are ≥65 years, there is little data on medical outcomes in older patients. We conducted a prospective multicentre cohort study of in- and outpatients ≥65 years, who have acute venous thromboembolism. All five Swiss university and four high-volume non-university hospitals participate in the study. Their goal is to determine the clinical and biological factors and processes of care that drive short- and long-term medical outcomes, health-related quality of life, and use of medical resources in elderly patients with acute venous thromboembolism.

METHODS

Elderly patients (≥65 years) with venous thromboembolism were enrolled in the cohort. We followed-up participants from October, 2012, to December, 2013. Follow-up included a telephone interview, two surveillance face-to-face evaluations during the first year, semi-annual contacts, and periodic review of patients' hospital charts. We collected blood samples from all participants at baseline and at 12 months follow-up and established a biobank. We extracted serum, plasma RNA and DNA from the blood. Blood samples were assayed with a standard haematology panel. They were processed and vialed within 1 h of collection and transported in batches to a central laboratory where they were stored at -80°C. The same laboratory analysed all the samples we collected. The primary medical outcome was recurrence of symptomatic, objectively confirmed venous thromboembolism during the follow-up period, defined as new or recurrent pulmonary embolism or deep vein thrombosis (proximal and/or distal).

CATEGORISER-FRAGEN

Fällt das Forschungsprojekt in den Geltungsbereich des Humanforschungsgesetzes?
Ja

BECAUSE
This project was based on a study protocol, which defined the exact procedures to be used. The study included a relatively large number of persons and was not based on individual cases ("method-driven search for generalizable knowledge"); thus, it is classified as research according to HRA). Adults (“persons”) who suffered from venous thromboembolism ("research concerning human diseases") were followed-up over 12 months. Researchers established a biobank with blood samples ("biological material") collected from all participants at enrolment and at 12 months. We extracted serum, plasma, DNA and RNA from the blood samples.

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Handelt es sich bei dem Forschungsprojekt um ein Projekt mit lebenden Personen?
Ja

BECAUSE
Adults ("persons") who suffered from venous thromboembolism were included in this research project.

Handelt es sich bei dem Forschungsprojekt um einen klinischen Versuch im Sinne der KlinV oder der KlinV-Mep?
Nein

BECAUSE
Researchers used telephone interviews, clinical exams and face-to-face visits to follow up adults ("persons") who suffered from venous thromboembolism. Researchers established a biobank with the blood samples they collected from all participants at enrolment and at 12 months. The study determined the recurrence of symptomatic, objectively confirmed venous thromboembolism during the follow-up period, defined as new or recurrent pulmonary embolism or deep vein thrombosis (proximal and/or distal). This project involved no health-related interventions (according to OClin).

Werden im Forschungsprojekt Massnahmen angewendet welche für die teilnehmenden Personen mit minimalen Risiken und Belastungen verbunden sind?
Ja

BECAUSE
Researchers used telephone interviews, clinical exams and face-to-face visits to follow up adults ("persons") who suffered from venous thromboembolism. Researchers established a biobank with the blood samples they collected from all participants at enrolment and at 12 months. The study determined the recurrence of symptomatic, objectively confirmed venous thromboembolism during the follow-up period, defined as new or recurrent pulmonary embolism or deep vein thrombosis (proximal and/or distal). The study used data collection procedures (phone interview, face-to-face meeting, and clinical examination) and blood sampling, which did not cause more than minimal risk or stress to participants.

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