KURZPROTOKOLL
ARTESiA

Öffentlicher Titel	Apixaban zur Verringerung der Thromboembolie bei subklinischem Vorhofflimmern
Wissenschaftl. Titel	Apixaban for the Reduction of Thrombo-Embolism in patients with Device-Detected Sub-Clinical Atrial fibrillation
Kurztitel	ARTESiA
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, zweiarmig
Studienphase	Phase III
Erkrankung	Herz und Kreislauf: Herzrhythmusstörung
Einschlusskriterien	- Permanent pacemaker or defibrillator (with or without resynchronization) or insertable cardiac monitor capable of detecting SCAF - At least one episode of SCAF >= 6 minutes in duration but no single episode > 24 hours in duration at any time prior to enrollment. Any atrial high rate episode with average > 175 beats/min will be considered as SCAF. No distinction will be made between atrial fibrillation and atrial flutter. SCAF requires electrogram confirmation (at least one episode) unless >= 6 hours in duration. - Age >= 55 years - Risk Factor(s) for Stroke: Previous stroke, TIA or systemic arterial embolism OR Age at least 75 OR Age 65-74 with at least 2 other risk factors OR Age 55-64 with at least 3 other risk factors - Other risk factors are: hypertension, CHF, diabetes, vascular disease (i.e. CAD, PAD or Aortic Plaque), female
Ausschlusskriterien	- Clinical atrial fibrillation documented by surface ECG (12 lead ECG, Telemetry, Holter) lasting 6 minutes, with or without clinical symptoms - Mechanical valve prosthesis, deep vein thrombosis, recent pulmonary embolism or other condition requiring treatment with an anticoagulant - Contra-indication to apixaban or aspirin: a. Allergy to aspirin or apixaban b. Severe renal insufficiency (creatinine clearance must be calculated in all patients; any patient with either a serum creatinine > 2.5 mg/dL [221 µmol/L] or a calculated creatinine clearance < 25 ml/min is excluded) c. Serious bleeding in the last 6 months or at high risk of bleeding (this includes, but is not limited to: prior intracranial hemorrhage, active peptic ulcer disease, platelet count < 50,000/mm3 or hemoglobin < 10 g/dL, recent stroke within past 10 days, documented hemorrhagic tendencies or blood dyscrasias) d. Moderate to severe hepatic impairment e. Ongoing need for combination therapy with aspirin and clopidogrel (or other combination of two platelet inhibitors) f. Meets criteria for requiring lower dose of apixaban AND also has ongoing need for strong inhibitors of CYP 3A4 or P-glycoprotein (e.g., ketoconazole, itraconazole, ritonavir or clarithromycin) g. Ongoing need for strong dual inducers of CYP 3A4 or P-glycoprotein (e.g., rifampin, carbamazepine, phenytoin, St. John's wort) - Received an investigational drug in the past 30 days - Participants considered by the investigator to be unsuitable for the study for any of the following reasons: a. Not agreeable for treatment with either aspirin or apixaban or anticipated to have poor compliance on study drug treatment. b. Unwilling to attend study follow-up visits c. Life expectancy less than the expected duration of the trial2 years due to concomitant disease - Women who are pregnant, breast-feeding or of child-bearing potential without an acceptable form of contraception in place (sterilization, hormonal contraceptives, intrauterine device, barrier methods or abstinence)
Alter	55 Jahre und älter
Sponsor	Hamilton Health Sciences

Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01938248 (primäres Register) EudraCT 2014-001397-33