KURZPROTOKOLL
Argatroban

Öffentlicher Titel	Untersuchung des Einflusses des Gerinnungshemmers Argatroban auf die elektrische Erregungsleitung im Herzen
Wissenschaftl. Titel	SAICoDis - Safety of Argatroban Infusion in Conduction Disturbances. A prospective, open, monocentric safety study to investigate conduction disturbances in patients receiving argatroban therapy.
Kurztitel	Argatroban
Studienart	Diagnostikstudie, multizentrisch, prospektiv, offen/unverblindet, einarmig, Pharma-Studie
Studienphase	Phase III
Erkrankung	Herz und Kreislauf: Herzrhythmusstörung
Einschlusskriterien	- Diagnosis of stable CAD or unstable angina (troponin negative, i.e. within the normal range for the study site) with low to moderate anatomic risk - Patient requires elective percutaneous coronary angioplasty or stent insertion with an approved device in one or more de novo-treated or re-stenotic lesions in native vessels - Patient is on adequate platelet inhibition therapy after receiving a loading dose with ASA and clopidogrel before start of intervention - Willingness to give written informed consent, written consent for data protection (legal requirement in Germany “datenschutzrechtliche Einwilligung”) and willingness to participate and to comply with the requirements of the study protocol - The patient (female/male) is at least 18 years of age - Baseline ECG without changes that impair assessment of QTc interval
Ausschlusskriterien	- Patient is indicated for highly complex 3-vessel intervention - The female patient is pregnant (exclusion by routine urine test) or is nursing during the therapy period - Patient who participates currently in another clinical trial or patients who participated in another clinical trial during the last 3 months prior to study start (date of treatment visit) - History of drug, alcohol or chemical abuse within 6 months prior to study start - Planned surgical intervention other than study procedure within 7 days after study start - Any condition, which contraindicates the use of argatroban, or endangers the patient if he/she participated in this study
Alter	18 Jahre und älter
Prüfzentren	**Innere Medizin 3** (Geschlossen) Kardiologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Studienzentrum Kardiologie Tel: 069 6301-83634 Fax: 069 6301-86092 studien-herzzentrum@unimedizin-ffm.de
Sponsor	Mitsubishi Tanabe Pharma GmbH
Registrierung in anderen Studienregistern	EudraCT 2016-003521-42