KURZPROTOKOLL
COVID-PREVENT

Öffentlicher Titel	Phase II Studie zu Rivaroxaban bei moderater bis schwerer Covid-19 Infektion und hohem Risiko auf Embolie
Wissenschaftl. Titel	Effect of Anticoagulation Therapy on Clinical Outcomes in Moderate to Severe Coronavirus Disease 2019 (COVID-19)
Kurztitel	COVID-PREVENT
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, zweiarmig
Studienphase	Phase II
Erkrankung	Gefäße: Gefäßverschluss (Thrombosen/Embolie) Infektionen: Virusinfektionen: SARS-Cov-2
Einschlusskriterien	- Subject must be willing, understanding and able to provide written informed consent - Subject must be a man or a woman with age > 18 years at screening - Subject must have an active moderate to severe COVID-19 confirmed by o A positive SARS-CoV-2 PCR test in the last 14 days - At least one of the following features should be present D-Dimer elevation > 1.5 ULN (age adjusted cut-offs) AND/OR Cardiac injury reflected by an elevation in hs-cTnT > 2.0 upper limit of normal (ULN) AND at least one of the following conditions: Known coronary artery disease (CAD) Known diabetes mellitus Active smoking - A woman of childbearing potential must have a negative serum or urine pregnancy test before randomization occurs. Before randomization, a woman must be either: Postmenopausal, defined as >45 years of age with amenorrhea for at least 18 months, If menstruating: If heterosexually active, practicing a highly effective method of birth control, including hormonal prescription oral contraceptives, contraceptive injections, contraceptive patch, intrauterine device, double-barrier method [(e.g., condoms, diaphragm, or cervical cap, with spermicidal foam, cream, or gel)], or male partner sterilization, consistent with local regulations regarding use of birth control methods for subjects participating in clinical studies, for the duration of their participation in the study, or Surgically sterile (have had a hysterectomy or bilateral oophorectomy, tubal ligation, or otherwise be incapable of pregnancy), or Not heterosexually active
Ausschlusskriterien	- Subject has a very high bleeding risk: Any condition that, in the opinion of the investigator, contraindicates anticoagulant therapy or would have an unacceptable risk of bleeding, such as, but not limited to, the following: Any bleeding (defined as bleeding requiring hospitalization, transfusion, surgical intervention, invasive procedures, occurring in a critical anatomical site, or causing disability) within 1 months prior to randomization or occurring during index hospitalization. Major surgery, biopsy of a parenchymal organ, ophthalmic surgery (excluding cataract surgery), or serious trauma (including head trauma) within 4 weeks before randomization. A history of hemorrhagic stroke or any intracranial bleeding at any time in the past, evidence of primary intracranial hemorrhage on CT or magnetic resonance imaging scan of the brain, or clinical presentation consistent with intracranial hemorrhage. This applies as well to subjects hospitalized for ischemic stroke upon randomization. Subject has a history of or current intracranial neoplasm (benign or malignant), cerebral metastases, arteriovenous (AV) malformation, or aneurysm. Active gastroduodenal ulcer, defined as diagnosed within 1 months or currently symptomatic or known AV malformations of the gastrointestinal tract. Platelet count <90,000/l at screening. Patients with the diagnosis of bronchiectasis, that due to the investigator judgement are at an increased bleeding risk

	- Subject has any of the following diseases in the medical history: Active cancer (excluding non-melanoma skin cancer) defined as cancer not in remission or requiring active chemotherapy or adjunctive therapies such as immunotherapy or radiotherapy. Chronic hormonal therapy (e.g. tamoxifen, anastrozole, leuprolide acetate) for cancer in remission is allowed. Any medical condition (e.g. atrial fibrillation) that requires use of any therapeutic parenteral or oral anticoagulant(s) (e.g. warfarin sodium or other vitamin K antagonists, Factor IIa or FXa inhibitors, fibrinolytics) concomitantly with study medication. Subject has known allergies, hypersensitivity, or intolerance to rivaroxaban or any of its excipients. Baseline eGFR <30 mL/min/1.73m2 calculated using CKD-EPI formula Known significant liver disease (e.g. acute hepatitis, chronic active hepatitis, cirrhosis) which is associated with coagulopathy or moderate or severe hepatic impairment. Known HIV infection - Subject has undergone any of the following procedures or received any of the following drugs: Received fibrinolysis during index hospitalization. Use of antiplatelet therapy with prasugrel or ticagrelor up to 7 days prior to randomization. Other P2Y12 antagonists can be given. However, the use of concomitant antiplatelet therapy should be carefully considered. ASS > 100 mg/d and continuous NSAIDs should be avoided. Use of dual antiplatelet therapy, such as aspirin plus clopidogrel during the study - Subject is a woman who is pregnant or breast-feeding - Known intolerance or history of hypersensitivity to the active substance or to any of the excipients of the Investigational Medicinal Product (IMP) - Subjects who are legally detained in an official institution - Subjects who may be dependent on the sponsor, the investigator or the trial sites, are not eligible to enter the trial
Alter	18 Jahre und älter
Sponsor	Universitätsmedizin Berlin, Charite
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT04416048 (primäres Register)