KURZPROTOKOLL
RECOVER

Öffentlicher Titel	Phase II Studie zur Plasmainfusion mit Covid-19 Antikörpern bei Covid-19
Wissenschaftl. Titel	A Randomized Open label Phase-II Clinical Trial with or without Infusion of Plasma from Subjects after Convalescence of SARS-CoV-2 Infection in High-Risk Patients with Confirmed Severe SARS-CoV-2 Disease
Kurztitel	RECOVER
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
Studienphase	Phase II
Erkrankung	Infektionen: Virusinfektionen: SARS-Cov-2
Einschlusskriterien	- PCR confirmed SARS-CoV-2 infection in a respiratory tract sample. - Oxygen saturation (SaO2) of 94 % or less while breathing ambient air or a ratio of the partial pressure of oxygen (PaO2) to the fraction of inspired oxygen (FiO2) of less than 300 mm Hg. - High risk due to either pre-existing or concurrent hematological malignancy and/or active cancer therapy (incl. chemotherapy, radiotherapy, surgery) within the last 24 months or less (group 1) and/or chronic immunosuppression not meeting the criteria of group 1 (group 2) and/or Age >= 50 - 75 years meeting neither the criteria of group 1 nor group 2 (group 3) and at least one of these criteria: Lymphopenia < 0.8 x G/l and/or D-dimer > 1g/mL and/or Age >= 75 years meeting neither the criteria of group 1 nor group 2 (group 4). - Blood hemoglobin concentration >= 8 g/dl. - Provision of written informed consent. - Patient is able to understand and comply with the protocol for the duration of the study, including treatment and scheduled visits and examinations. - Male or female patient aged >= 18 years. - Postmenopausal or evidence of non-childbearing status. For women of childbearing potential: negative urine or serum pregnancy test within 14 days prior to study treatment.
Ausschlusskriterien	- Dementia, psychiatric or cognitive illness or recreational drug/alcohol use that in the opinion of the principle investigator, would affect subject safety and/or compliance. - Contraindication to transfusion or history of prior reactions to transfusion blood products. - Patients with known selective IgA deficiency. - Patients with mechanical ventilation and/or extracoporal membrane oxygenation (ECMO) at time of initial inclusion into the trial. - Participation in another trial with an investigational medicinal product. - Treatment with SARS-CoV-2 convalescent plasma in the past.
Alter	18 Jahre und älter
Prüfzentren	**Innere Medizin 2** (Geschlossen) Infektiologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Franziska Ebeling
Sponsor	Universitätsklinikum Heidelberg
Registrierung in anderen Studienregistern	EudraCT 2020-001632-10