KURZPROTOKOLL
B-pVAC

Öffentlicher Titel	Phase I/II Studie zur Multi-Peptid-Impfung zur Vorbeugung einer COVID-19-Infektion bei Erwachsenen mit B-Zell-/Antikörper-Mangel
Wissenschaftl. Titel	B-pVAC-SARS-CoV-2: Phase I/II multi-center safety and immungenicity trial of multi-peptide vaccination to prevent COVID-19 infection in adults with B-cell/antibody deficiency
Kurztitel	B-pVAC
Studienart	multizentrisch, prospektiv, offen/unverblindet, einarmig, Investigator Initiated Trial (IIT)
Studienphase	Phase I/II
Erkrankung	Blut: Myeloische Neoplasien/Dysplasien: Chronische myeloische Leukämie (CML) Blut: Non-Hodgkin-Lymphome (NHL), niedrig-maligne: weitere Blut: Akute myeloische Leukämie (AML): weitere Blut: Multiples Myelom: weitere Blut: Myeloische Neoplasien/Dysplasien: Chronische myelomonozytäre Leukämie (CMML) Blut: Hodgkin-Lymphome: weitere Blut: Myeloische Neoplasien/Dysplasien: Myelodysplastische Syndrome (MDS) Blut: Myeloische Neoplasien/Dysplasien: weitere Blut: Non-Hodgkin-Lymphome (NHL), hoch-maligne: weitere Blut: Akute lymphatische Leukämie (ALL): weitere Blut: Non-Hodgkin-Lymphome (NHL), niedrig-maligne: Chronische lymphatische Leukämie (CLL) - sonstige Studien Blut: Myeloische Neoplasien/Dysplasien: Myeloproliferative Neoplasien (MPN)
Einschlusskriterien	- Adult (>=18 years) male or non-pregnant, non-lactating female - Primary antibody deficiency syndrome or Secondary antibody deficiency syndrome, defined by one of the following: - 1. IgG < 5.5 g/l - 2. Ongoing substitution of immunoglobline for hypogammaglobinemia - 3. Anti-CD20 antibody (monospecific) therapy for malignant disease: - 3a. after combined Anti-CD20 antibody therapy with chemotherapy (e.g. fludarabin, cyclophosphamid, bendamustin, anthracycline, vincristin) (within 1-6 months post therapy) - 3b. ongoing or up to 6 months after single agent Anti-CD20 antibody therapy - 3c. ongoing or up to 6 months after combined Anti-CD20 antibody therapy with BTKinhibitors or BCL2-inhibitors - 3d. Anti-CD20 antibody maintenance therapy - Ability to understand and voluntarily sign an informed consent form - Ability to adhere to the study visit schedule and other protocol requirements - Female patients of child bearing potential (FCBP) and male patients with partners of child bearing potential, who are sexually active, must agree to the use of two effective forms (at least one highly effective method) of contraception. This should be started from the signing of the informed consent and continue until three months after vaccination. Furthermore, contraception must be carried on by patients receiving B-cell depleting therapies for the whole duration of the treatment - Postmenopausal or evidence of non-child-bearing status. For women of childbearing potential: negative urine or serum pregnancy test within 7 days prior to study treatment. Postmenopausal or evidence of nonchildbearing status is defined as: - 1. Amenorrhoea for 1 year or more following cessation of exogenous hormonal treatments - 2. Luteinizing hormone (LH) and Follicle stimulating hormone (FSH) levels in the postmenopausal range for women under 50

Ausschlusskriterien	- Pregnant or lactating females - Participation in any clinical trial with intake of any investigational or non-registered vaccine product - Any concomitant disease affecting the effect of the therapeutic vaccine or interfering with the study primary endpoint: - 1. Active infection - 2. Psychiatric disorders - 3. Known systemic anaphylaxis - Prior or current infection with SARS-CoV-2 as assessed by medical history, or by throat/nose swab (PCR) or serologically documented immunization against SARS-CoV-2 (after infection or vaccination) - persisting symptoms developed after vaccination against SARS-CoV-2 with one of the approved vaccines-products - HIV infection, chronic or active hepatitis B or C - History of relevant CNS pathology or current relevant CNS pathology (e.g. seizure, paresis, aphasia, cerebrovascular ischemia/haemorrhage, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, psychosis, coordination or movement disorder, excluding febrile seizures as child) - Baseline laboratory CD4+ T cell count < 100 µl - The following pre-existing medical conditions: - 1. Chronic liver failure defined as Child-Pugh Score >=B - 2. Chronic renal failure defined as GFR <40 ml/min/1,73m2 - 3. Serious pre-existing cardiovascular disease such as NYHA >= III - 4. Sickle cell anemia - Known hypersensitivity to any of the components included in the CoVac-1 vaccine - Pre-existing auto-immune disease except for Hashimoto thyroiditis and mild (not requiring immunosuppressive treatment) psoriasis - Patient receiving active treatment with Proteosome- Inhibitors (e.g. Bortezomib), Phosphoinositid-3-Kinase-Inhibors (e.g. Idelalisib) - Patient receiving active treatment with small molecules, including Tyrosine Kinases-Inhibitors (e.g. Ibrutinib), Proteosome-Inhibitors (e.g. Bortezomib), Bcl-2-Inhibitors (Venetoclax) or Phosphoinositid-3-Kinase-Inhibors (e.g. Idelalisib) - Intention of receiving one dose of an already approved vaccine against SARS-CoV-2 before day 56
Alter	18 Jahre und älter
Sponsor	Universitätsklinikum Tübingen
Registrierung in anderen Studienregistern	EudraCT 2021-001070-38 (primäres Register)