

1. General Information

Cohort ID	5002_21
Title (Study Name)	The CoVVac Study - Humoral and cellular immune response to COVID-19 vaccines in immunocompromised and healthy individuals
Principal investigator	Assoc. Prof. Martin Stradner
Contact information	pm-biobank@medunigraz.at
Funding agency	none

2. Description

<p>This study will characterize and analyse the anti-SARS-CoV-2 humoral and cellular immune response before and after vaccination with a focus on the anti-spike protein response in immunocompromised patients compared to healthy controls. The cohort study includes 189 adult participants with primary or secondary immunodeficiencies (suffering from haematological and rheumatic diseases) and 187 healthy control subjects.</p> <p>Blood and saliva samples will be obtained before (visit 1) and after (visit 3-6) vaccinations.</p> <p>Visit 1 (60-0 days before vaccination): Serology, immune status, t-cell immunity, t-cell aging Visit 2 (0-14 days after first vaccination): Telephone visit to get information on vaccination reactions Visit 3 (+21-28 days after 2nd vaccination): Serology, t-cell immunity, nutritive assessment, body fat composition Visit 4 (+6 months after 2nd vaccination): Serology Visit 5 (+3-6 weeks after V4 or 3rd vaccination): Serology, t-cell immunity Visit 6 (+6 months after Visit 4): Serology, t-cell immunity, nutritive assessment, body fat composition</p> <p>Date and type of COVID-19 vaccinations, medical history (including immunosuppressive therapies, chronic GvHD, severe opportunistic infections, prior vaccination history (types, titers if available), current and past disease including COVID-19), current medication, BMI, smoking habits, and nutritive assessment will be obtained for all participants.</p>
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3. Details

ICD 10/O codes / Healthy	M05, D38, M34, C90, C91.1, C92, D46 /healthy	
Key words	COVID-19 vaccination, immunocompromised, t-cell immunity, t-cell aging,	
Collection / Cohort size 12/2022	6.061 serum aliquots, 3.862 PBMC aliquots and 1.419 saliva aliquots from 376 patients	
Informed Consent (IC)	<input checked="" type="checkbox"/> Broad Biobank IC	
	<input checked="" type="checkbox"/> Specific Study IC	
Status	<input checked="" type="checkbox"/> In progress / compl. date: 05/2024	
	<input type="checkbox"/> Completed	
Inclusion criteria	Age distribution	18+
	Sex distribution (f:m)	~ 50:50
	Others	<ul style="list-style-type: none"> • Healthy • Primary or secondary immunodeficiencies
Earliest access	As of now	
Quality-standards	<input checked="" type="checkbox"/> ISO 9001:2015 (SOPs)	

Associated publications / references	<p><u>CD19+IgD+CD27- Naïve B Cells as Predictors of Humoral Response to COVID 19 mRNA Vaccination in Immunocompromised Patients</u> Schulz E, Hodl I, Forstner P, Hatzl S, Sareban N, Moritz M, Fessler J, Dreo B, Uhl B, Url C, Grisold A J, Khalil M, Kleinhapfl B, Enzinger C, Stradner M H, Greinix H T, Schlenke P, Steinmetz I; https://www.frontiersin.org/articles/10.3389/fimmu.2021.803742/full</p> <p><u>Altered cellular immune response to vaccination against SARS-CoV-2 in patients suffering from autoimmunity with B-cell depleting therapy.</u> Hodl I, Sallegger C, Forstner P, Sareban N, Moritz M, Dreo B, Schulz E, Lackner A, Kleinhapfl B, Hatzl S, Moazed-Fürst F, Seifert-Held T, Heschl B, Khalil M, Enzinger C, Greinix H, Stradner MH, Steinmetz I, Schlenke P, Fessler J. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9850844/</p>
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4. Material available (aliquot size) and storage conditions

Material	<input checked="" type="checkbox"/> Serum (4 x 580 µl)	<input checked="" type="checkbox"/> -80°C	<input type="checkbox"/> liq. N ₂
	<input checked="" type="checkbox"/> PBMC's (4 x 1800 µl)	<input type="checkbox"/> -80°C	<input checked="" type="checkbox"/> liq. N ₂
	<input checked="" type="checkbox"/> Saliva (1 x 100 µl)	<input checked="" type="checkbox"/> -80°C	<input type="checkbox"/> liq. N ₂

Dokument erstellt (tt/mm/yyyy): 17/06/2021	Letzte inhaltliche Aktualisierung (tt/mm/yyyy): 09/08/2023
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