1. Introduction, purpose of the registry

On the morning of March 12, 2020, the World Health Organization (WHO) announced the outbreak of the new coronavirus disease 2019 (COVID-2019) pandemic. By the time the protocol was written, according to a summary report from Johns Hopkins University, a total of more than 4,444,670 cases had been confirmed in 188 countries and the epidemic had claimed the lives of 302,493 people. This trend predicts that the epidemic is still far from peaking. As with other infectious diseases, some cases occur asymptomatically or with mild symptoms and therefore remain undiagnosed. Thus, it is difficult to accurately estimate the true incidence and outcome of the disease. An analysis of 72,314 Chinese patients with the SARS CoV-2 epidemic found that 5% of the population required intensive care unit (ICU) treatment, with the most common indications being acute respiratory failure, septic shock, and / or multiple organ failure. Similar data were reported from Italy. Two days after the outbreak in Italy, 60% of the ICU beds in the Lombardy region had COVID-19 patients, a situation that has since deteriorated significantly. Based on Chinese data, the clinical presentation of COVID-19 shows a milder course, out of 2143 infected children, only one died and in most cases a mild course was observed, however, similar to adults, 5.9% had a critical illness requiring ICU care.

The purpose of the registry and biobank is to understand the development, epidemiology, diagnosis, symptomatology, and therapy of SARS-CoV-2 infection, as well as to investigate biomarkers and map the genetic background.

In the case of a new patient, the data can be uploaded prospectively, in the case of a patient diagnosed before the start of the registry, in order to complete the epidemiological data, retrospectively.

The registry is suitable for recording every step of patient care from the diagnosis of infection, and can be used to document both mild or severe disease.

The recording of patient data in the registry does not affect the patient's medication and diagnostic tests, the patient does not receive any drugs in the experimental stage during the study.

2. Patient Involvement

2.1. Duration

01/05/2020-15/04/2025

2.2. Planned number of patients

Taking into account the epidemiological data, the trend in the spread of the virus predicts that the epidemic is still far from peaking, however, the exact incidence cannot be estimated at present. Furthermore, the number of patients involved depends largely on the number of PCR tests performed and the willingness to participate. Nationwide, 5,000 confirmed infected cases are planned to be involved during the pandemic.

2.3. Involvement criteria

All patients who have confirmed or suspected SARS-Cov-2 infection.

2.4. Exclusion criteria

Without consent, the patient cannot be included in the prospective data and sample collection. The patient or his / her legal representative withdraws his / her voluntary consent during the study.

2.5. Informing patients

Prior to the start of the study, all patients will provide written consent, if possible. The person providing the information shall inform the patient in detail about

- the purpose and course of the research
- that the patient's consent to the research is voluntary (which can be withdrawn at any time orally or in writing and in this case, clinical data relating to him will no longer be used even anonymously in patients whose data are collected prospectively)

in a way that is comprehensible to the patient, based on the information prepared by the research coordinator. The patient may contact the research coordinator at any time and ask further questions.

3. Biological sampling

In addition to the data, a biological sample is taken from the patients in cases where blood sample is taken for other reasons (eg monitoring of the clinical condition) on the recommendation of the specialist in charge of care. In the event that the patient does not have a blood sample during care, he/she can give written consent which allows for blood sampling for solely research purposes.

3.1. Sampling and purpose

Whole blood: Taken in 1x 6 ml EDTA blood collection tube. For children, the amount per kilogram of body weight (3 ml to 4 ml). DNA is isolated from the blood, from which we look for rare genetic variants that are known to predispose to infectious diseases and a more severe course of the disease is expected in individuals under genetic load.

Serum and plasma: 2 x 8.5 ml (5 ml for children) serum separator tube and 1x 6ml EDTA blood collection tube are taken on several days of hospitalization (1st, 2nd, 3rd day, than every second day, from day 10 every third day and at the ending day of hospitalization). We plan to investigate IL6, IL12, TNFα, and other biomarkers related to inflammation and other pathophysiology that are not available in routine laboratory diagnostics on a daily basis.

Saliva: From 2 ml of saliva samples we plan to detect various antibodies (immunoglobulins such as IgA).

3.2. Storage of samples

The biological samples are stored at -80°C in the biobank of the University of Pécs(UP) Clinical Centre Department of Medical Genetics for later examination. They are processed at the UP Clinical Centre Department of Laboratory Medicine and at the UP Szentágothai Research Center.

Whole blood: 2x1,8ml cryo tube

Serum: 6x1,8ml cryo tube

Plasma: 1x1,8 cryo tube

Saliva: 2ml

4. Data collection

4.1. Data source

If the patient is hospitalized the data is collected from the hospital documentation during the hospitalization or directly after the hospital discharge. If the patient does not need hospital care, we document the parameters of the disease based on a daily telephone interview until the initial symptoms cease.

4.2. Data quality and input

Patient data are recorded on an electronic patient data collection sheet according to the appendix. Data recording and verification are performed by trained clinical research administrators.

4.3. Data handling

Through the Internet, each workplace can only manage its own data.

4.4. Evaluation

The data collected during the study are evaluated with the involvement of statisticians and SPSS programs.