



**Tyumen Cardiology Research Center, Tomsk National Research Medical Center, Russian
Academy of Science, Tomsk, Russia**

One-year Cardiac Follow-up of COVID-19 Pneumonia (159)
Study Protocol

13/07/2020

Brief Summary: The primary objective of the study is to assess the cardiac status of COVID-19 pneumonia patients during 1 year after discharge.

Although COVID-19 manifests in most cases with respiratory symptoms, cardiovascular abnormalities are common in hospitalized patients. Patients with cardiovascular risk factors or established disease appear to have a worse prognosis. Myocardial dysfunction could represent a direct manifestation of COVID-19. Investigation of the long-term cardiovascular consequences of COVID-19 is needed. Subjects after COVID-19 pneumonia can present myocardial remodeling for a long time after discharge, even in the absence of prior cardiovascular disease.

Keywords: Covid19; Cardiovascular Disease; Echocardiography

Hypothesis: In patients with COVID-19 pneumonia initiates and aggravates the processes of structural and functional remodeling of the myocardium within 1 year after discharge from the hospital.

Primary Outcome Measure:

Echocardiographic assessment of cardiac function. Echocardiographic assessment of global strain parameters at 3 and 12 months after discharge

[Time Frame: up to one year]

Secondary Outcome Measures:

1. MACCE. Major adverse cardiac and cerebrovascular events: cardiac death, myocardial infarction, or stroke at 3 and 12 months after discharge

[Time Frame: up to one year]

2. Quantitative analysis of parenchymal lung damage. Describe the parenchymal lung damage through a quantitative analysis with chest CT at 3 and 12 months after discharge

[Time Frame: up to one year]

3. Functional exercises capacity assessment. Six-min walk test at 3 and 12 months after discharge

[Time Frame: up to one year]

4. Evaluation of renal function. Measure of creatinine clearance at 3 and 12 months after discharge

[Time Frame: up to one year]

5. Evaluation of inflammation. Analysis for C-reactive protein at 3 and 12 months after discharge

[Time Frame: up to one year]

6. Evaluation of coagulation abnormality. Analysis for activated clotting time at 3 and 12 months

[Time Frame: up to one year]

7. Evaluation of quality of life in first year after discharge. Assessment of the Short Form Health Survey (SF36) at 3 and 12 months after discharge

[Time Frame: up to one year]

The objective of the study is to evaluate the impact of COVID-19 pneumonia on transthoracic echocardiography and other myocardial parameters during 1 year follow-up to monitor cardio-vascular events and predict outcomes.

Population. According to the protocol, the study included men and women ≥ 18 years old with documented COVID-19 pneumonia 3 month \pm 2 week after discharge. The sample size is 380 people (calculation by the Cochran method and Raosoft calculator). The observation period was 12 months \pm 2 weeks. The planned terms of inclusion in the study are the end of December 2020.

Design: The prospective observational study includes men and women ≥ 18 years old who were 3 month \pm 2 week ago discharged after documented COVID-19 pneumonia. Patients were identified from medical information system of local COVID hospital between April and December 2020. The study will be performed in accordance with the International Conference on Harmonization of Good Clinical Practice and the Declaration of Helsinki. The study protocol was approved by the local ethics committee (Approval Number: 159 from 07/23/2020). Every patient is explained the purpose of the study and benefits of participation. If the patient agrees to participate in the study, he signs an informed consent. All patients included have negative results on a swab test at the end of the hospitalization. Exclusion criteria were impossibility to follow up, cancer, tuberculosis. Patients undergo clinical, instrumental and laboratory diagnostics tests during follow-up visits at 3 and 12 month \pm 2 week after discharge, and telephone interview at 6 month after discharge to collect information on health status, outcomes and treatment adjustments.

The study protocol does not provide for a single way for patients managing. If any cardiovascular abnormalities or other disturbances found 3 months after discharge, the therapy carried out.

At the visit of 3 and 12 months, the patient is interviewed (complaints, data of the epidemiological and medical history), clinical examination, anthropometry, measurement of temperature, heart rate, blood pressure, oxygen saturation, dyspnea, myalgia are performed. Based on the data obtained, the diagnosis is specified (arterial hypertension, coronary artery disease, arrhythmias, obstructive pulmonary disease, asthma, obesity, metabolic syndrome, diabetes mellitus, obliterating atherosclerosis and others); the basic therapy is adjusted. Each patient undergoes electrocardiography, general and biochemical blood tests, microalbuminuria test. Lungs CT, echocardiography with myocardial strain assessment, six-minute walk test, assessment of symptoms of stress, anxiety and depressive disorders (PSS-10 GAD7, PHQ9, respectively) are performed. According to diagnosis, patients are divided into groups. Examination at visits of patients in 12 months after discharge is carried out according to the approved examination plan in groups. During the observation, the incidence of adverse cardio-cerebral events (MACCE) and the prognostic value of the structural and functional parameters of the myocardium and blood vessels will be assessed.