Recruitment of participants for the "Study on SARS-CoV-2 Antibody Titer Measurement in Human Serum and Utilization of the Results"

This gives the details for the "Study on SARS-CoV-2 Antibody Titer Measurement in Human Serum and Utilization of the Result". You will not be disadvantaged even if you do not participate in this study. If anything is not clear, please do not hesitate to ask the person in charge.

1. Outline of the study

Title of the study:

Study on SARS-CoV-2 Antibody Titer Measurement in Human Serum and Utilization of the Result

Research institute and the principle investigator:

The study will be performed by following research institute and the principle investigator.

Research institute:

The University of Tokyo

Principle investigator:

Shintaro Yanagimoto, Professor, Division for Health Service Promotion

Responsibility:

Supervision and organization of the study

Study duration:

Five years from date of approval

Aim of the study:

The novel coronavirus infection epidemic which was first reported in December 2019 is still continuing. Reverse transcription polymerase chain reaction (RT-PCR) is generally performed to confirm the presence or absence of the infection. Measures against the infection usually consists mainly of prevention and treatment. However, currently measures against the infection route, such as avoiding the 3Cs (confined spaces with poor ventilation, crowded places and close contact) are the only method. When effective vaccines are developed, as is the case with measles, and with established measurement and utilization of antibody tests, it may be possible to control the infection based on individual or herd immunity from the perspective of public health.

There are currently no effective vaccines against the pathogenic virus of the novel coronavirus infection (SARS-CoV-2). The measurement of antibody titer has become widely used overseas, and the study to evaluate the significance and the way of its utilization are ongoing. Clinical tests for antibody titer measurement against SARS-CoV-2 does not exist in Japan. We will be using the serum antibody titer measurement which utilizes the antigen-antibody reaction approved for clinical use overseas to measure the positive rate of SARS-CoV-2 antibody among the study population. Unlike the simple measurement kit which only gives qualitative result of only negative or positive, this method will quantify the results. This method is expected to enable a more accurate evaluation. Combined analysis of the antibody titer results and questionnaire along with the data from the health check-ups, we plan to explore the effective measures to utilize the antibody titer test for the public health tactic against the novel coronavirus infection.

Study method:

We will collect blood in the usual manner following which we will perform statistical analysis of the answers to the questionnaire, information from the health check-ups kept in the University of Tokyo Health Service Center. We may ask you to answer a second questionnaire and collect more blood about a year after the first participation (we may not perform second blood collection if the study protocols are changed). There is no obligation to participate a second time just because you participated in the first study participation. You may choose to participate in the second study or not freely.

The blood collected for one study will be one collecting tube (standard blood collection volume 5 ml). Any physical harm that you may experience with the blood collection will be the same as the normal blood collection for your routine health check-up. If you participate to the study on the same day as your health check-up, we will collect your blood for the study at the same time with your blood for the health check-up (standard blood collection volume 5 ml). Analysis of the blood will be limited solely to the titer of the serum antibody and we will not perform any genetic evaluation. We may, however, examine the RNA or antigen of the novel coronavirus in the blood, when infection is suspected.

For this study, we would like to encourage the participation in our study of anyone who has been in contact with those who have been infected by the novel coronavirus through employment at the university, disposition of your duty for those who work as the primary duty or subsidiary work at a medical facility. If you fall in this category, please apply to participate in the study. We will analyze the association between the antibody titer and any events between the blood sampling for those who participate in the study more than once.

The medical meaning of the antibody titer measurement is currently not known. A positive result may be proof of past infection and/or immunization, but this has not been proven yet. We will inform the result to any participant who wishes to know. However, please continue with the lifestyle preventing the spread of the novel coronavirus infection regardless of the result.

If you wish to obtain and read the study protocol or study method to know the study in detail, please contact us using the details given at the end. We will provide the information in a manner that does not interfere with the protection of personal data of the other participants or the security of the originality of the study.

2. Voluntary participation in the study and freedom of withdrawal

Your participation to the study is based on your free will. If you wish to withdraw from the study after giving your consent to participate in the study, simply submit the signed withdrawal of consent form to the contact given below. You will not be disadvantage due to non-participation in the study. Your study sample and results will be discarded following to your withdrawal. However, any data already published as analyzed results will not be discarded even if you withdraw your consent. Those under 20 years old must obtain the agreement of their guardian/parents to participate, but they may withdraw their consent on their own will.

3. Protection of personal data

We pay the utmost attention to the protection of personal data and respect the privacy of the

participants in the study so that they are not disadvantaged. The study samples, information, and data collected in association with the study will be treated with care so that they are not leaked outside. Personal information such as names, addresses, birthdates, etc. are removed and newly coded so that it cannot be identified (anonymized) and kept under lock.

4. Publication of the study result

The results of the study will be published at a scientific meeting or on a scientific journal and released on database anonymized so that personal information such as names cannot be specified. In case of personal questions, we will report individual study results and/or the results of the whole study. The results of the test and analysis of the study, however, are not established for the meaning or the accuracy at the moment.

5. Benefit and disadvantage to the study participants

The possibility of the study providing immediate beneficial information to the study participants are low. We will measure the titer of the antibody which are thought to be associated with the novel coronavirus infection and the results will be reported to the participants. The test is not authorized as a clinical test for the diagnosis of the infection at the timing of the study. It is not clear whether or not the results are associated in any way with past infections or future immunity.

The actual physical involvement of the study participants will solely be in the collection of blood samples. The expected harm will only be the pain experienced during blood collection, which is within its limit and is thought to be minimal. The blood collection will be done in the usual manner. In case of any complications such as swelling or numbness, they will be treated appropriately.

In the event of a situation we need to advise a participant to visit a medical institution including the health service center for reasons which are not related to the study participation such as blood collection, the costs are to be borne by the study participant.

6. Policy for handling of information after the completion of the study

Information collected for the study will be kept for five years from the termination of the study to be used as an important resource to implement new studies, under the condition of your consent. However, in the event you withdraw your consent to participate to the study the information will be immediately discarded except for the information analyzed using anonymized data. When the data will be used for a new study, we will acquire a new approval from the ethics committee of the University of Tokyo.

7. Your burden of costs

There will be no cost burden for the blood collection or analysis to participate the study. The measurement result will be reported from the health service center or test department of the hospital. There will be no honorarium for participating in the study. As mentioned above, there may be recommendations to visit a medical institution including the health service center for the reason other than your study participation. In this case, the cost is to be borne by the study participant.

8. Others

This study will be implemented with the approval of the ethics committee of the University of Tokyo. The cost of the study is being paid from the operating costs of the University of Tokyo. There are no conflict of interests which need to be disclosed.

After the start of the study, you may withdraw your consent to participate the study due to changes in the study method. The information regarding the details of changes in the study will be made available on the website given below.

If you have any questions or any concerns, please do not hesitate to contact us.

Contact details:

Principal investigator:

Shintaro Yanagimoto, Professor, Division for Health Service Promotion

Contact person:

Shintaro Yanagimoto, Professor, Division for Health Service Promotion

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