

“Development of countermeasure for 2019 novel coronavirus infection”

Japan Self-Defense Forces Central Hospital and co-research institutions conduct the research title of “Development of countermeasure for 2019 novel coronavirus infection”.

The purpose of research is that to clarify the viral characteristics of novel coronavirus (COVID-19) and development of diagnostics methods to use the clinical information and clinical specimen have taken from the patients infected with COVID-19. This research will contribute to the improvement of the clinical outcome, countermeasure for the COVID-19 in the future.

This research protocol, human rights, and safety were reviewed and approved by Institutional Review Boards of Self-Defense Forces Central Hospital and co-research institutions.

Contents

- Approval number:
- The term of the clinical research: from the date on which approval was obtained to 30/Mar/2022.
- Main researcher: Kazuyasu Miyoshi (Department of Internal Medicine, Self-Defense Forces Central Hospital)
- Co-research institutions: National Institute of Infectious Diseases, National Center for Global Health and Medicine, Toshima Hospital, Tokyo Metropolitan Bokutoh Hospital, Tokyo Metropolitan Cancer and Infectious Diseases Center Komagome Hospital, Kameda Medical Center, Ebara Hospital, National Defense Medical College, and Japanese Red Cross Musashino Hospital.

Introduction of COVID-19

The outbreak of COVID-19 have been started from Wuhan, China, and some patients with infected with COVID-19 have been confirmed in all around the world. The clinical impact of COVID-19 is still unknown. Therefore, the appropriate clinical diagnosis and countermeasure for COVID-19 is important to prevent the further outbreak.

However, COVID-19 is new infectious disease, hence, the clinical and viral characteristics of COVID-19 is unknown. It is urgent needed for pathologic clarification

of COVID-19. We conduct the collected and analysis of the clinical information, clinical findings (Blood test, Chest X-ray, CT scan) and virus in the clinical specimen (saliva, pharyngeal swab, and sputum, and blood) to improve the clinical outcome for further patients, and report the these results.

Voluntary participation

Your participation in this research is completely voluntary. It is your choice whether to participate or not. If you choose not to participate, all the services you receive will continue and nothing will change.

You have the right to refuse or withdraw at any time. If you withdraw this study, your information and specimens will be deleted according to your wishes. However, this rule does not apply to all cases where the research article has already been published.

Type of research intervention

The clinical findings have been recorded at the medical record and clinical specimens have been taken from the patients (hospitalization and out patients) are used for the study. Your information will be anonymizes to be not specified your private information. The term of the clinical research: from the date on 1/Jan/2020 to which approval was obtained.

Confidentiality

The information we collect from this research project will remain private. Only the investigators will know what your information is and we will close that information with a padlock and a key. Your information will be anonymizes to be not specified your private information.

Information disclosure

The research results will be published and reported as academic conference presentation with the anonymization to prevent your and your family name being specified.

Cost

You do not need to bear a cost, and will not be rewarded. There is no conflict of interest, which leads to disadvantage of participants or unfairly evaluation of research.

Intellectual property rights

The intellectual property rights which will be obtained from this research belong to the researcher and research institute, not participants.

Who to contact

If you have any questions, you can ask the responsible researcher.

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Document declaring the withdrawal of consent

“Development of countermeasure for 2019 novel coronavirus infection ”.

To Self-defense Force Central Hospital

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I inform you the withdraw consent to this research.

I withdraw consent to following contents with marked.

- My clinical information is used of research
- My sample and specimen are used of research for detection of virus.

Name of the

participant_____

Participant's signature _____ Date _____

Day /month / year ____ / ____ / _____