

# "Now is the time to use ivermectin," said Haruo Ozaki, chairman of the Tokyo Metropolitan Medical Association.

2021/08/19 10:55

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## POINT

- Although papers have been published one after another that ivermectin is effective in both prevention and treatment of the new corona, its use has not progressed in Japan, which has already been regarded as a "country of use".
- It should be used now that the infection explosion is progressing, but there are problems such as lack of ivermectin and not being covered by the government's side effect damage relief system.
- If the Japanese version of EUA is prepared quickly and can be used by doctors in the field, it can be administered to patients waiting at home or undergoing medical treatment. The government should actively promote its use.

Delta strains of Indian origin raged during the Tokyo Olympics, and the number of infected people continues to increase. Why is Japan not trying to use ivermectin, which has few reports of side effects and has been reported to be effective in clinical trials in other countries? On August 5, we had an urgent interview with Mr. Ozaki, chairman of the Tokyo Metropolitan Medical Association, who had been proposing effective uses of ivermectin from early on.

Wen Keshou · Constituted NPO Corporation · Chairman of the 21st Century Concept Research Association  
Science journalist Rensei Baba



## | The peak of infection spread that is not yet visible

—It seems that the explosive spread of infection, which is also called the 5th wave, is still rising. The number of people waiting at home and receiving medical treatment is increasing rapidly. How is the Tokyo Metropolitan Medical Association responding?

"When the number of people waiting at home and receiving medical treatment increased sharply in the third wave of January, this was no good, and the Tokyo Metropolitan Medical Association and the Tokyo Metropolitan Medical Association worked together to build a system with the goal of 24-hour support. We are now able to handle up to 37 of the 47 district medical associations. However, the current situation where more than 1000 home caregivers are piled up every day is beyond the limit. , Vaccination, medical examination, home visit, etc. are not available. Now, the health center is coordinating hospitalization. There is also a hospitalization coordinating center in Tokyo, but there is a system that can quickly accept and treat suddenly changed corona patients. I haven't gotten to the point of being established. "

## Many clinical trial results are "effective for prevention and treatment"

--If you read the papers on clinical trials of ivermectin that have been published around the world, there are many examples that are effective for both prevention and treatment.

"I am aware that there are many papers that ivermectin is effective in the prevention and treatment of corona, mainly in Central and South America and Asia. There is no effective therapeutic drug, although it is necessary to deal with patients who develop it one after another. The vaccine is not in time. At such an imminent time, there is a paper that ivermectin is effective for corona, so it is a natural response for clinicians to try using it. Doctor-led clinical practice That's why many test papers came out. "

Ivermectin

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--Usually, pharmaceutical companies conduct large-scale clinical trials to see the effect, but ivermectin is a silver bullet for tropical diseases such as onchocerciasis (river blindness) and lymphatic filariasis, and the World Health Organization (WHO) is used. It is a drug approved by countries around the world more than 20 years ago. If the new corona is also effective, it is not applicable, but it is unavoidable that we decided to use it in a pandemic.

"That's right. The medical field of a pandemic is a battlefield. It's the same as a field hospital. Patients are brought in and their condition deteriorates one after another and they die. So I can understand the feelings of the doctor who clings to this and administers it. "

"The other day, a research group at the All India Institute of Medical Sciences / AllMS, which sets guidelines for the treatment of corona infections in India, has published a paper investigating the preventive effects of ivermectin. According to the report, about 3,900 medical workers (staff and students) were given 0.3 mg / kg of

clinical trials divided into three groups of those who did not, it is said that those who received ivermectin twice reduced the new corona infection by 83%. It was the first time in the world to publish a paper. It's a class research group, so it's very reliable. "

## Japan has already been classified as a country of use

--In Japan, ivermectin is permitted to be used for the treatment of COVID-19 from the "Guide for the Treatment of Coronavirus Infection (COVID-19), Second Edition" notified on May 18, 2020. In the world, Japan is classified as a country that uses ivermectin.

"In Japan, skin diseases have been around for a long time. scabies For example, ivermectin has been approved as an indication under the brand name "Stromector", and the revised guide has issued a notice to approve the treatment of the new corona as "off label". Off label means that it may be used at the discretion of the doctor and the patient. By the time the notification was issued, 36 clinical trials were conducted in 27 countries around the world, and it was reported that ivermectin was effective in prevention and treatment. That is why the Ministry of Health, Labor and Welfare also admitted that it is not applicable. If it doesn't work, no notification will be issued. "

## The government is willing to use the parliamentary response, but ...

--In the Diet, the government is responding to promote the use of ivermectin.

"At the House of Representatives Budget Committee on February 17, Katsuhito Nakajima, a member of the Constitutional Democratic Party, said that ivermectin should be" fully backed up in clinical trials so that the country can approve it as a treatment for corona as soon as possible. " Mr. Tamura, Minister of Health, Labor and Welfare, replied, "It can still be used for non-adaptive use. There is also a usage of taking it at a medical institution and waiting at home." Prime Minister Kan said, "It is extremely for Japan. I think it's an important drug, so I'll do my best. "

—Why can't you?

"We also investigated what kind of supply system Merck & Co., Inc. of the United States, which supplies Japanese approved drugs, has. Maybe because Merck & Co. is developing a therapeutic drug, ivermectin is a new corona. With the view that it is not effective for the treatment and prevention of sickness, there is an intention that it

effective for the treatment and prevention of sickness, there is an intention that it should not be used for anything other than skin diseases such as scab. It doesn't lead to the supply of ivermectin. Even if a doctor writes a prescription for ivermectin, there is no drug in the pharmacy. This is virtually unusable. "

"But (Merck) says that ivermectin doesn't work, so there shouldn't be any need to limit supply. If it doesn't work, there's no demand. I believe it works, so block supply. It looks like you are. "

## ■ The reason why generics are not popular

--Ivermectin generic drugs are also manufactured in large quantities in China and India. If Merck doesn't come out, there should be a way to import and supply it.

"That's right. If the" Special Measures Bill for Designation and Use of Specific Drugs for the Treatment of New Influenza, etc. "(Japanese EUA \* Maintenance Bill), which was submitted to the House of Representatives by Representative Nakajima, who is also a doctor, is passed, generic products But I think the government isn't working at all at this point. "

"The other problem is that ivermectin has already been used in many countries around the world, and its dosage, dosage, safety and efficacy have been confirmed, but it has not yet been done in clinical trials in Japan. For this reason, ivermectin is not covered by the drug side effect relief system. This makes it difficult for doctors to use. However, even in such anxiety and disadvantageous situations, doctors who are convinced of the effects of ivermectin. Some of us are prescribing ivermectin at our own risk. I hope that the Japanese version of the EUA maintenance law will be enacted as soon as possible. "

\* EUA (Emergency Use Authorization) A system of the US Food and Drug Administration (FDA) that permits the use of unapproved drugs in an emergency and expands the indications for approved drugs. The FDA is <1> a life-threatening disease <2> a certain degree of effectiveness is recognized in the treatment of diseases, etc. <3> The benefits of using it outweigh the potential risks of the product <4> Other diseases It is approved for use if it is determined that there is no suitable alternative to diagnose, prevent, or treat.

## ■ Although it is a country of use, it cannot be used in reality



Chairman Ozaki (right) responding to the author's interview

—Since you admitted that it is not applicable, Japan is classified as an "Ivermectin user country" in the world, but it is a system that can not be used in reality.

"That's right. In short, the government has not built a system that can supply ivermectin, so it is not a promotion system. If the Japanese version of EUA is prepared quickly and it becomes a system that can be used by doctors in the field, As Minister of Health, Labor and Welfare Tamura replied in the Diet, it can actually be administered to patients who are waiting at home or undergoing medical treatment, but with the current system, virtually nothing can be done. However, if we remain cautious in the event of such an emergency, we can only understand that we are sacrificing the safety of the people. "

## Academic sites and researchers who do not touch themselves

--Are there any other problems in Japan?

"Ivermectin is a drug discovered by Dr. Satoshi Omura and won the Nobel Prize. Japan should be the first in the world to work on whether it really works for corona. WHO and the National Institute of Public Health (NIH) in the United States continues to take the view that the effect on corona is uncertain, but since ivermectin is used all over the world in the pandemic, the country is conducting clinical trials that can obtain

scientific evidence. If you take the initiative and draw objective and convincing conclusions, it will lead to an increase in the level of research in Japan. "

"A group of American clinicians (FLCCC) has announced that ivermectin is effective against corona in South America, Asia, etc., and a group of doctors such as the British Ivermectin Recommendation Group (BIRD) has compiled many papers. I was convinced that it was "effective" from the meta-analysis analyzed in the above, and recommended ivermectin to medical sites around the world. I also told the Japan Olympic Committee that ivermectin should be used effectively when holding the Tokyo Olympics. But the government didn't do anything. "

"There are also problems with academic researchers and university professors. Doing nothing on their own," Ivermectin is uncertain whether it works for corona, issued by international organizations such as WHO and large Western health organizations. There are many people who take the view of "Ivermectin" as their own view. Instead of doing it independently, it works only by the opinions of others. It's sad that there are critics, researchers, and scholars who just criticize without doing anything. I hope Japanese academia will contribute more positively. "

## ■ Tokyo Metropolitan Medical Association "wants to work on use"

--In Japan, a clinical trial led by Kowa, a major pharmaceutical company, is finally planned. How will you respond?





Governor of Tokyo Yuriko Koike and Chairman Ozaki (left) respond to media coverage after an opinion exchange meeting for the development of a vaccination system in January 2021.

"The Tokyo Metropolitan Government and the Medical Association have a policy of actively supporting and cooperating with this clinical trial. We have decided to actively seek out and provide medical institutions to cooperate with. We rely on vaccines and therapeutic agents developed by foreign countries. There is nothing we can do in the country where we are. It is our duty to properly collect ivermectin data by ourselves and aim to contribute to the reduction of serious illness and mortality from Japan. "

--What should the Japanese medical system learn from the experience of the corona pandemic?

"Under the universal health insurance system in Japan, it became clear that it would be difficult to respond to a pandemic emergency like this one. Private medical facilities are managed by maximizing the occupancy rate and improving efficiency. Under such circumstances, it is extremely difficult to say. "Because the number of infected people

has increased rapidly, take action" like this time. "

"To give an example of countermeasures, we built a hospital with about 1000 empty beds in public medical institutions and hospitals, and usually operate it as a training and training institution for research facilities, doctors, nurses, and laboratory technicians. , There is a method of utilizing it as a medical institution when a pandemic occurs. We will hone our skills and train human resources, and when a pandemic occurs, we will create a system that can also put in the trained human resources. I think there are issues, but I think we should consider and research in the future. "

## After the interview

### Repulsion to WHO, which is cautious about use

With the Delta strain (Indian mutant) trying to replace almost all infected people in Japan, the number of newly infected people of the new corona is reaching a record high every day.

There are more than 20,000 home recuperators in Tokyo and more than 70,000 nationwide. Katsuhito Nakajima, a member of the House of Representatives who is also a doctor, emphasizes that "antibody cocktail therapy is effective, but there are problems in securing the amount and establishing a system. It is necessary to expand the options for early treatment to prevent the aggravation of corona patients." I felt that one of the options was the administration of ivermectin, which strongly moved Chairman Ozaki.



Tedros WHO Secretary-General

The evaluation of ivermectin for the treatment and prevention of corona has not yet been finalized. Major health organizations around the world, such as the WHO and NIH, maintain the view that "there are no clinical trial results that provide enough evidence to convince scientists around the world." However, it is also true that there are many groups of doctors in the United States and the United Kingdom who argue that "these claims are unfounded."

With some people becoming severely ill and dying, doctors are working hard day and night in medical settings around the world. The medical field in India during the period of rapid spread of infection was just a battlefield. In the medical field where neither therapeutic agents nor therapeutic devices are sufficient, ivermectin was administered based on many papers that it was effective for the new corona, and there were many cases where it had a great effect.

The Indian Bar Association has created a document that strongly criticized WHO's disapproval of ivermectin for therapeutic use as "a murder crime that kills patients" and sent it to Secretary-General Tedros and Chief Scientists to send the document to the world. It has been announced for.

The medical groups that have the effect of ivermectin are FLCCC in the United States and BIRD in the United Kingdom. FLCCC summarizes the results of a meta-analysis (as of August 15) of 63 clinical trials conducted by 613 scientists (doctors / researchers) around the world on 26,398 people as follows. Judging.

- ▽ 86% preventive effect in 14 preventive trials
- ▽ 73% improvement effect in 27 initial symptom treatment trials
- ▽ 40% improvement effect in 22 severe treatment trials
- ▽ 61% mortality in 25 clinical trials Decline in rate

Approximately half of the 31 meta-analyzed trials are standardized in clinical trials worldwide and are evidence-oriented randomized controlled trials (RCTs), which show a 60% improvement effect. Chairman Ozaki said that it would be okay for some clinicians to believe this and use ivermectin for treatment.

## || The claim to deny ivermectin is also deep-rooted

On the other hand, it is a fact that there are deep-rooted voices that question or oppose the use of ivermectin for the treatment and prevention of corona. The author

has read three papers claiming that there is no ivermectin effect, two of which have been pointed out by researchers as incorrect clinical trial methods. Isn't there any other treatise that says it has no effect?

Certainly, a treatise by a group of Egyptian doctors who said it was "effective" has data. <sup>Netsuzo</sup> Forgery In some cases, it was pointed out that there was a suspicion that it was done and it was withdrawn. However, as mentioned above, the fact that there are overwhelmingly many papers that ivermectin is effective for the new corona remains unwavering. Ivermectin has few side effects, is generic and cheap. The idea of trying it out is not reckless. Denying the use may destroy the countermeasures against the pandemic.

## || Expectations for the enactment of the Japanese version of the EUA bill

Minister of Health, Labor and Welfare Tamura replied in the Diet that "it can still be used for off-label use. There is also a way to take (ivermectin) at a medical institution and wait at home." If this can be done easily, the Tokyo Metropolitan Medical Association should not have to bother to insist that "ivermectin should be used."

Chairman Ozaki said, "Off-label use is not covered by the relief system even if there are health hazards due to side effects, etc., and first of all, there is nothing to prescribe." Unless generics become available, ivermectin will continue to be a "drug that cannot be used forever" in reality.

Overcoming that barrier is the enactment of the "Japanese EUA Development Bill" submitted to the Diet by members of the House of Representatives Katsuhito Nakajima of the Constitutional Democratic Party, who is also a doctor. However, it is still on the shelf due to the recess of the Diet.

"If this bill is passed, everything will be resolved," said the lead proponent, Representative Nakajima. Ivermectin, a treatment for scabies, can be used to treat corona, opening the way for the use of generics, and relieving health hazards such as side effects. He believes that doctors will be willing to prescribe this.

The vaccination rate for the entire Japanese population has not reached about 50% for the first time and 40% for the second time. The biggest concern of Chairman Ozaki of the Tokyo Metropolitan Medical Association, which has the largest local population in Japan, is the medical facilities that accept critically ill patients. <sup>Pull</sup> force It is a countermeasure against the sudden change in the condition of home recuperators.

In the words of Chairman Ozaki, there was a sense of crisis that there was no choice but to make ivermectin available urgently.

Discovered in Japan, ivermectin has the potential to become the "savior" of the corona pandemic. Looking at the clinical trial reports in the world so far, it cannot be said that it does not work at all. Many countries, including India, have a track record of urgently administering ivermectin to control the spread of infection. In an emergency, I decided to use it for corona infection <sup>Chucho</sup>hesitation I don't see any reason to do it. I am convinced that the use of ivermectin is by no means a "bet".



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## Profile

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### Haruo Ozaki ( Ozaki, Haruo )

Director of Ozaki Internal Medicine and Cardiovascular Clinic. We have been particularly focusing on tobacco control that is effective in preventing illness and frailty syndrome in order to prevent the need for long-term care. As the chairman of the Tokyo Metropolitan Medical Association, he continues to request and propose new corona countermeasures to the government, Tokyo Metropolitan Government, and medical institutions. Graduated from Juntendo University, 69 years old.



## Profile

### Baba drilling Mr. ( Baba-drilling )

Born in 1940. After working at the Yomiuri Shimbun Social Affairs Department, Science Department, and Commentary Department, he was an editorial writer. After leaving the company, he has served as a professor at the Graduate School of Intellectual Property, Tokyo University of Science, a visiting professor at Waseda University, a visiting researcher at the National Institute of Science and Technology Policy, Ministry of Education, Culture, Sports, Science and Technology, and a member of the Cabinet Office General Science and Technology Council. Currently, the chairman of the 21st Century Concept Study Group, a certified NPO. "Is it okay? Japanese manufacturing" (President), "Is it okay? Japanese patent strategy" (same as above), "100 years of the Nobel Prize" (Chukoron-Shinsho), "Satoshi Omura, a chemist who protected 200 million people from illness" (Chuokoron-Shinsha), "The IP Nation is Dangerous" (Co-author: Nihon Keizai Shimbun Publishing Co., Ltd.) and many other books.

### I want to read it together

- ▶ Is "Delta Co., Ltd." made by Moderna more effective than Pfizer?
- ▶ Corona aggravation risk, lowest is type O ... highest is
- ▶ Domestic vaccine can be supplied for 60 million people a year ... Shionogi Pharmaceutical "Mass production system will be ready by the end of the year"
- ▶ Expert dissatisfaction explosion, new corona subcommittee overturned "Shangshan general meeting"

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