Test ID jRCT2031200120

Last updated: November 7, 2021

jRCT

Placebo-controlled randomized double-blind (evaluators, patients) multi-facility joint parallel group comparison trial to examine the efficacy and safety of Ivermectin for COVID-19 patients

Basic information

test ID	jRCT2031200120	
Scientific Title (Acronym)	Placebo-controlled randomized double-blind (evaluators, patients) multi-facility joint parallel group comparison trial to examine the efficacy and safety of Ivermectin for COVID-19 patients	A placebo-controlled, randomized, double-blind study in COvid-19 patients with iveRmectin; An inVEstigator iniTiaTEd trial
Public Title (Acronym)		double-blind study in COvid-19 patients with iveRmectin
Exam progress/Recruitment status	Call for participants has ended - the exam is ongoing.	not recruiting
registration date and time	September sixteenth, 2020	
Last updated date	November 7, 2021	
Test start date (scheduled date)	September 16, 2020	
Examination end date (planned date)	March 31, 2022	
Date of first enrollment	September sixteenth, 2020	

Exam summary

Test area / Region	Japan	Japan
Implementation prefecture	Tokyo	

Target number of cases/ Target sample size	240	
Target disease / Health condition(s) or Problem(s) studied	COVID-19	COVID-19
Study type	intervention	Interventional
Study design		
Randomization		
intervention 1	Ivermectin group: About 200μg/kg of Ivermectin is administered on a single oral day 1 (on an empty stomach) Placebo group: Placebos that do not contain Ivermectin as ingredients are administered on a single oral day 1 (on an empty stomach) Subjects will use the study drug (Ivermectin 3mg tablets) or the contrast drug (Ivermectin pla) on Day 1. Take Sebo tablets) per subject's weight.	
intervention two	Ivermectin group: About 200μg/kg of Ivermectin is administered on a single oral day 1 (on an empty stomach) Placebo group: Placebos that do not contain Ivermectin as ingredients are administered on a single oral day 1 (on an empty stomach) Subjects will use the study drug (Ivermectin 3mg tablets) or the contrast drug (Ivermectin pla) on Day 1. Take Sebo tablets) per subject's weight.	
intervention three	Ivermectin group: About 200μg/kg of Ivermectin is administered on a single oral day 1 (on an empty stomach) Placebo group: Placebos that do not contain Ivermectin as ingredients are administered on a single oral day 1 (on an empty stomach) Subjects will use the study drug (Ivermectin 3mg tablets) or the contrast drug (Ivermectin pla) on Day 1. Take Sebo tablets) per subject's weight.	
intervention four	Ivermectin group: About 200μg/kg of Ivermectin is administered on a single oral day 1 (on an empty stomach) Placebo group: Placebos that do not contain Ivermectin as ingredients are administered on a single oral day 1 (on an empty stomach) Subjects will use the study drug (Ivermectin 3mg tablets) or the contrast drug (Ivermectin pla) o	

	n Day 1. Take Sebo tablets) per subjec t's weight.	
intervention five	Ivermectin group: About 200μg/kg of I vermectin is administered on a single oral day 1 (on an empty stomach) Placebo group: Placebos that do not co ntain Ivermectin as ingredients are ad ministered on a single oral day 1 (on a n empty stomach) Subjects will use th e study drug (Ivermectin 3mg tablets) or the contrast drug (Ivermectin pla) o n Day 1. Take Sebo tablets) per subjec t's weight.	
intervention six	Ivermectin group: About 200μg/kg of I vermectin is administered on a single oral day 1 (on an empty stomach) Placebo group: Placebos that do not co ntain Ivermectin as ingredients are ad ministered on a single oral day 1 (on a n empty stomach) Subjects will use th e study drug (Ivermectin 3mg tablets) or the contrast drug (Ivermectin pla) o n Day 1. Take Sebo tablets) per subjec t's weight.	
intervention seven	Ivermectin group: About 200μg/kg of I vermectin is administered on a single oral day 1 (on an empty stomach) Placebo group: Placebos that do not co ntain Ivermectin as ingredients are ad ministered on a single oral day 1 (on a n empty stomach) Subjects will use th e study drug (Ivermectin 3mg tablets) or the contrast drug (Ivermectin pla) o n Day 1. Take Sebo tablets) per subjec t's weight.	
intervention eight	Ivermectin group: About 200μg/kg of I vermectin is administered on a single oral day 1 (on an empty stomach) Placebo group: Placebos that do not co ntain Ivermectin as ingredients are ad ministered on a single oral day 1 (on a n empty stomach) Subjects will use th e study drug (Ivermectin 3mg tablets) or the contrast drug (Ivermectin pla) o n Day 1. Take Sebo tablets) per subjec t's weight.	
intervention nine	Ivermectin group: About 200μg/kg of I vermectin is administered on a single oral day 1 (on an empty stomach) Placebo group: Placebos that do not co ntain Ivermectin as ingredients are ad ministered on a single oral day 1 (on a n empty stomach) Subjects will use th e study drug (Ivermectin 3mg tablets)	

	or the contrast drug (Ivermectin pla) o n Day 1. Take Sebo tablets) per subjec t's weight.	
intervention ten	Ivermectin group: About 200μg/kg of I vermectin is administered on a single oral day 1 (on an empty stomach) Placebo group: Placebos that do not co ntain Ivermectin as ingredients are ad ministered on a single oral day 1 (on a n empty stomach) Subjects will use th e study drug (Ivermectin 3mg tablets) or the contrast drug (Ivermectin pla) o n Day 1. Take Sebo tablets) per subjec t's weight.	
Main evaluation items / Primary outcomes	The period until COVID-19 PCR test (S ARS-CoV-2 nucleic acid detection) bec omes negative	Period until the COVID-19 PCR test (S ARS-CoV-2 nucleic acid detection) be comes negative
Secondary outcomes	1) Appearance rate of cases whose me dical condition has changed between D ay 1 and Day 15 (evaluated by 7-point order scale) Order scale; 1 No pneumo nia, no restrictions on daily life movem ents (PS0) 2 No pneumonia, limited da ily life movements (PS1 or higher) 3 P neumonia, no oxygen inhalation 4 Pne umonia, oxygen inhalation 5 Non-invas ive auxiliary ventilation therapy or hig h flow oxygen inhalation therapy 6 Arti ficial respiration management available (including ECMO use) seven deaths D efinition of changes in the condition; t he following changes in clinical conditi ons are defined as changes in the cond ition. (1) Changes from 1 to 2 levels o r more (2) Changes from 2 or 3 to 1 le vel or more Definition of pneumonia; shading is recognized in simple chest X -rays or chest CT, and there are no ob vious factors other than pneumonia su ch as heart failure as the cause. Standard for daily life movement restri ctions; 0 is not limited to daily life mo vements according to the following crit eria, and 1 or more is limited to daily l ife movements. ECOG (Eastern Cooper ative Oncology Group) Performance St atus (PS) Score definition 0 You can w ork without any problems at all. You ca n do the same daily life as before the onset without restrictions. 1Physically i ntense activities are limited, but they can walk, and light work and sitting wo rk can be done. Examples: light house work, office work 2 You can walk, and you can do everything around you, but you can't work. More than 50% of the	1) Occurrence rate of cases in which t he condition changed between Day1 a nd Day15 (evaluation by 7-p oint ordi nal scale) Ordinal scale; 1 No pneumo nia, no restrictions on activities of dai ly living (PS0) 2 No pneumonia, limite d daily activities (PS1 or higher) 3 Wi th pneumonia, no oxygen inhalation 4 With pneumonia and oxygen inhalatio n 5 With non-invasive assisted ventila tion or high-flow oxygen inhalation th erapy 6 With artificial respiration man agement (including ECMO use) seven death" Definition of change in medica l condition; The following change in cl inical condition is defined as change i n medical condition. (1) Change from 1 by two or more steps (2) Change fr om 2 or 3 by one or more steps Definition of pneumonia: A chest X-ra y film or chest CT shows a shadow, a nd there is no obvious caus e other th an pneumonia such as heart failure. Criteria for restricting activities of dai ly living; 0 is not restricted to activiti es of daily livi ng and 1 or more is res tricted to activities of daily living acc ording to the following criteria." Table 11.2 ECOG (Eastern Cooperative Onc ology Group) Performance Status (PS) Grade Ecog Performance Status 0 F ully active, able to carry on all pre-di sease performance without restriction 1 Restricted in physically strenuous a ctivity but ambulatory and able to car ry out wo rk of a light or sedentary n ature, e.g., light house work, office w ork 2 Ambulatory and capable of all s elfcare but unable to carry out any w

	daytime spends time outside the bed. 3 I can only do things around myself with limitedness. Spend more than 50% of the day in bed or chair. 4 I can't move at all. I can't do anything around me at all. Spend time completely in bed or chair. five deaths Source: Oken, M. M., et al., Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol, 1982. 5 (6): p. 649-55. Evaluator; the principal investigator or the investigator's trial share at each facility becomes the assessor. In order to unify the evaluation criteria, the evaluation method will be unified at the startup meeting. 2) Percentage of pneumonia development in Day 15 and survival follow-up period 3) Percentage of oxygen inhalation required 4) Percentage and number of days required for artificial respiratory management 5) Changes in body temperature until Day 15 6) Negative rate of SARS-CoV-2 PCR up to Day 15 7) Total death until the end of the tracking period 8) Percentage and number of days of rescue treatment started until Day 15 9) Percentage and days of developing serious dynamic vein thrombosis such as cerebral infarction and pulmonary blood clots 10) Adverse events [Safety evaluation items: Adverse events observed in self-awareness findings (patient findings at the time of examination), vital signs (blood pressure, pulse rate, body temperature), clinical test values] 11) The number of days it took to normalize oxygen saturation in indoor air when oxygen inhalation is required (SpO2≥95% lasts for 24 hours) 12) The number of cases that have improved at least one level from 3, 4 to Day 15 in the clinical condition (order scale) in eligibility test (at the time of registration)	ork activities; up and about more than 50% of waking hours 3 Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours 4 Completely disabled; cannot carry on any selfcare; totally confined to bed or chair five dead Source: Oken, M.M., et al., Toxicity and response criteria of the Eastern Cooperative Oncology Group . Am J Clin Oncol, 1982. 5 (6): p. 649-55. Evaluator: The Principle investigator or sub-investigator in each facility will be the evaluator. In order to unify the evaluation criteria, the evaluation method will be unified at the startup meet ing." 2) Percentage of pneumonia on Day 15 and survival follow-up period 3) Percentage requiring oxygen inhalation 4) Percentage and number of days requiring artificial respiration management 5) Changes in body temperature up to Day 15 6) Negative rate of SARS-CoV-2 PCR up to Day15 7) All deaths until the end of the follow-up period 8) Percentage and number of days rescue treatment started up to Day 15 9) Percentage and number of days of severe arteriovenous thrombosis such as cerebral infarction and pulmonary thrombosis 10) Adverse events [Safety evaluation items: subjective findings (patient findings at the time of examination), vital signs (blood pressure, pulse rate, body temperature), adverse events observed in c linical laboratory values] 11) Number of days required for normalization of oxygen saturation in indoor air (SpO2>=95% lasting 24 hours) when oxygen inhalation was required 12) The number of cases in which clinical status (sequential scale) 3, 4 on Day 1 improved by more t han one stage on Day 15"

eligibility

Age minimum	over twenty years old and over	>= 20age old
Age (upper limit) / Age maximum		not applicable
Gender	both men and women	both
Selection criteria / Include criteria	1) A person diagnosed with COVID-19 (including asymptomatic) due to COVID-19 PCR test (SARS-CoV-2 nucleic aci	1) A person who has been diagnosed with COVID-19 (including asymptomatic) by the COVID-19 PCR test (SARS

	d detection) within 3 days before the e ligibility test. 2) Those with oxygen sat uration (SpO2) of indoor air is 95% or more. 3) A person who is 20 years old or older when obtaining consent. 4) Th ose who weigh more than 40 kg during eligibility tests. 5) A person who unde rstands the contents of the Study and obtains written consent to participatio n in the Study.	-CoV-2 nucleic acid detection) within 3 days before the qualification test. 2) A person with oxygen saturation (S pO2) in the room air of 95% or more. 3) A person who are 20 years or older at the time of obtaining consent. 4) A person who weighs 40 kg or more a t the time of qualification test. 5) A p erson who understands the content of this clinical trial and can obtain writte n consent to par ticipate in the clinica l trial.
Exclude criteria	1) A person who is breastfeeding, preg nant, or a woman who may be pregnan t, or who does not agree to contracepti ve medically by appropriate means unt il seven days after the administration of the study drug. Medically appropriat e contraception means not conducting sexual negotiations, treatment of surgi cal infertility by cetectomy, or use in c ombination with two or more of the int rauterine contraceptives, oral contrace ptives, and condoms. 2) Serious liver damage (AST or ALT at the time of elig ibility test is more than 3 times the fac ility reference value upper limit and to tal bilirubin is more than twice the faci lity base value upper limit), kidney dis order (eGFR of eGFR of equalification t est value is 30 mL/min/1.73 m2 or les s) Those who have. 3) A person who h as an irritable disease against Ivermec tin. 4) Those who have serious drug all ergies such as Stevens Johnson syndro me and addictive epidermal necrosis. 5) A person who has received a prohibit ed drug within the past month (within the past 6 months for biological prepar ations), or those who need to use proh ibited drugs during the study period. 6) A person who is planning to get SAR S-CoV-2 vaccinated from the date of c onsent to the end of the tracking perio d. 7) A person currently participating i n another clinical trial, or who has part icipated in another clinical trial within 30 days before obtaining consent. 8) O ther persons who the principal investig ator, etc. deems inappropriate as a sub ject of the Study.	1) A woman who is in lactation period or who may be pregnant, or those w ho do not agree to prevent p regnanc y by medically appropriate means for up to 7 days after study drug adminis tration. Medically appropriate contrac eption means that using a combinatio n of two or more of the following: not having sexual intercourse, taking sur gical sterilization such as vasectomy or intrauterine devic e, taking oral co ntraceptive, using condom. 2) A pers on who has severe liver damage (AST or ALT at the time of qualification test is more than 3 times the upper limit of institutional standard and total bilir ubin is more than twice the upper li mit of institutional standard value), r enal disorder (eGFR of eligibility test value 30 mL/min/1.73m 2 or less). 3) A person with hypersensitivity to iver mectin. 4) A person with a history of severe drug allergies such as Stevens -Johnson syndrome, toxic epiderma l necrolysis. 5) A person who has recei ved the prohibited medication within t he past month (within the past 6 mon t hs for biologics), or those who need to use the prohibited medication duri ng the clinical trial peri od. 6) Those who are scheduled to receive SARS-C oV-2 vaccination from the date of con sent to the end of the follow-up perio d. 7) A person who are currently parti cipating in other clinical trials or who have participated in oth er clinical trials within 30 days before obtaining consent. 8) In addition, a person who is determined to be unsuitable as a s ubject of this clinical trial by t He prin cipal investigator."

responsible researcher

Name of lead principal investigator	Kunihiro Yamaoka	Kunihiro Yamaoka
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Implementation Responsible Organization / Affiliation	Kunihiro Yamaoka	Kitasato University Hospital
Funding Source		Japan Agency for Medical Research and Development, Kitasato Institute
Joint Implementation Organization / Funding Source		
reception ID		

Examination inquiry window

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Ethics Review Committee

Name of the Certified Clinical Research Review Committee or Ethics Review Committee	Kitasato University Shirokane Clinical Trial Review Committee	
Certification number of the above committee		
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Examination reception number	two thousand seven
Results of the examination for the clinical research	approval
Approval date of the accredited clinical research review committee	August 14, 2020

In case of change or cancellation

Cancellation notification date	
date of cancellation date	
Reason for discontinuation	

in case of termination

End notification date	
Observation period end date	
Number of cases implemented	
Participant flow	
Background information of researchers	
Summary of the occurrence situation of diseases, etc.	
Data analysis and results of major evaluation items and secondary evaluation items	
Scheduled release date	
summary	
URL of the research plan	
Date of presentation in the first publication on the results	

URL about the results and publications	

IPD data sharing

Plan to share data (IPD) for each research subject	
Description of the plan	

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