Regarding consent

Please decide voluntarily whether to participate in this study or not, after being given sufficient explanation of the clinical study from your treating physician and having fully understood this explanation. You may consult your family and friends. Please take time in considering this matter.

Objectives of this clinical study

This clinical study involves 2 types of treatments (both treatments use the same drugs, however the administration route is different with intravenous or peritoneal administration) using 2 types of drugs called paclitaxel and carboplatin and aims to compare the effects and the adverse effects of these treatments in patients who are diagnosed with stage II, III, and IV epithelial ovarian cancer; fallopian tube cancer; or primary peritoneal cancer in order to investigate which treatments are better for the patients. The details of the study are explained later.

The following explanations apply to patients with ovarian cancer; however, epithelial ovarian cancer, fallopian tube cancer, and primary peritoneal cancer are all very similar in nature. Peritoneal cancer occurs in the peritoneum and fallopian tube cancer occurs from the epithelium of the fallopian tube, however these disorders have the same etiology as the epithelial ovarian cancer. It is known that chemotherapy (therapy using anti-cancer drugs), which is effective in ovarian cancer, is also effective in these types of cancer.

If you have been diagnosed with fallopian tube cancer or primary peritoneal cancer, replace the words "ovarian cancer" with "fallopian tube cancer" or "primary peritoneal cancer" while reading this information.

Estimated number of patients who participate in the study and the planned study period

This clinical study started in May 2010 in Japan. Approximately 654 patients with the same condition as you will be participating in the study. The treatment period will vary for each patient; however, it will be about 5 to 7 months. There is a follow-up period of about 6.5 years set aside after the treatment for regular observation of the patient conditions.

Background of this clinical study

As early diagnosis methods have not been established for ovarian cancer and symptoms are difficult to detect in the early stage, 60% or more of the

patients diagnosed with the disorder already have cancer spread across their abdomen. For this reason, ovarian cancer is considered one of the cancers that are relatively difficult to treat.

The standard treatment (which is considered the best treatment at present) for advanced ovarian cancer involves surgical removal of the tumor followed by the administration of anti-cancer drugs. Usually, two types of drugs, paclitaxel and carboplatin are administered as intravenous drip every 3-4 weeks for approximately 6 times. However in reality, more than half of the patients experience a recurrence of the cancer after this treatment, and development a more effective treatment is in urgent need.

In 2008, the result of a Japanese clinical study was reported that compared (i) traditional treatment involving intravenous drip of paclitaxel and carboplatin every 3 weeks, and (ii) new treatment where a relatively small dose of paclitaxel is administered intravenously every week and carboplatin is administered by intravenous drip every 3 weeks. The results showed improved prognosis in patients who had undergone the new treatment (ii). This finding has gotten attention globally.

Ovarian cancer often spreads to the whole of the abdominal cavity (the abdomen). For this reason, the method of administering anti-cancer drugs into the abdominal cavity was developed a few decades ago. This method is expected to be highly effective, as it involves application of a much higher concentration of anti-cancer drugs compared to intravenous administration directly to the tumor. Also, the adverse reaction in this treatment are expected to be lighter compared to intravenous administration where the anti-cancer drugs only take effect after spreading to the whole body.

In the last 10 years or so, a large number of patients with ovarian cancer from Europe and the United States have participated in a number of clinical studies on the peritoneal administration of anti-cancer drugs. The results have demonstrated that risk of death in patients with ovarian cancer is decreased by 21.6% for peritoneal administration of anti-cancer drugs when compared with intravenous administration. The findings are attracting major attention. From the results of clinical studies that have been conducted up to now, the treatment method considered most effective is (iii) 3-weekly intravenous administration of paclitaxel and 3-weekly peritoneal administration of cisplatin (platinum preparation in the same group as carboplatin) and paclitaxel. However, this treatment is associated with strong adverse reactions, such as nausea, vomiting, or abdominal pain, and

because of this a treatment with less adverse reactions is being investigated currently. Of the newly investigated treatments, combination therapy of intravenous paclitaxel and peritoneal carboplatin is one of the therapies with the high expectations. A number of small-scale clinical studies have been conducted for this treatment in Japan already, and satisfactory results have been reported, along with a small incidence of adverse effects. However, at present it is not known whether intravenous administration or peritoneal administration is more beneficial.

Therefore, in order to establish a more effective chemotherapy with fewer adverse reactions, we have planned this clinical study to compare the following:

Treatment I:

Weekly intravenous drip of paclitaxel with relatively small dose, combined with 3-weekly intravenous drip of carboplatin

Treatment II:

Weekly intravenous drip of paclitaxel with relatively small dose, combined with 3-weekly peritoneal administration of carboplatin

Specific details regarding this clinical study

1. Drugs used

In this clinical study, the patients will be treated with 2 drugs, paclitaxel and carboplatin, which are both used widely across the world for treating ovarian cancer. These drugs are also used widely for other types of cancer.

2. Requirements and procedures before the start of the study treatment

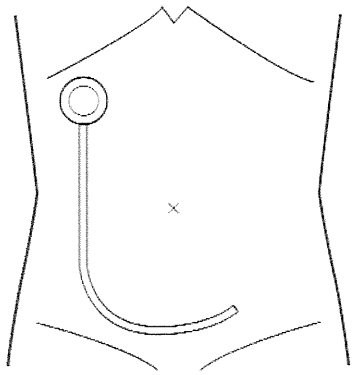
If you agree to participate in the study, we will conduct examination such as blood tests and ECG before the surgery to check if your current condition is suitable for this study. In some cases, we may use the results of examinations that have been conducted before your consent is obtained for study participation. If we find from the examination results that you are not suitable for participation in this study, your participation will be cancelled even if you agreed to participate. This will also apply to cases where the surgery results indicate that you are not suitable for participating in this study. In these cases, your treating physician will explain other treatments that are considered the best for you.

If you are participating in this study, a decision must be made during (or after) the surgery as to whether carboplatin is administered intravenously

or via the abdomen. The type of treatment you will undergo will be determined not by yourself or your treating physician, but by neutral means using a computer (called randomization) in order to eliminate bias at a third party institution (Kitasato University Research Center for Clinical Pharmacology, Clinical Trial Coordinating Center: iPocc Trial Center, 5-9-1 Shirokane, Minato-ku, Tokyo Japan). The patients will be allocated so that the conditions of the patients (stage, tumor size, etc.) in the treatment groups will be uniform to the extent possible, in order to compare the two treatment types. You may question why the patients or the treating physicians cannot make choices on the treatment method used; however, this method is adopted in clinical studies worldwide as being the best method of investigating what types of treatment are most effective or beneficial.

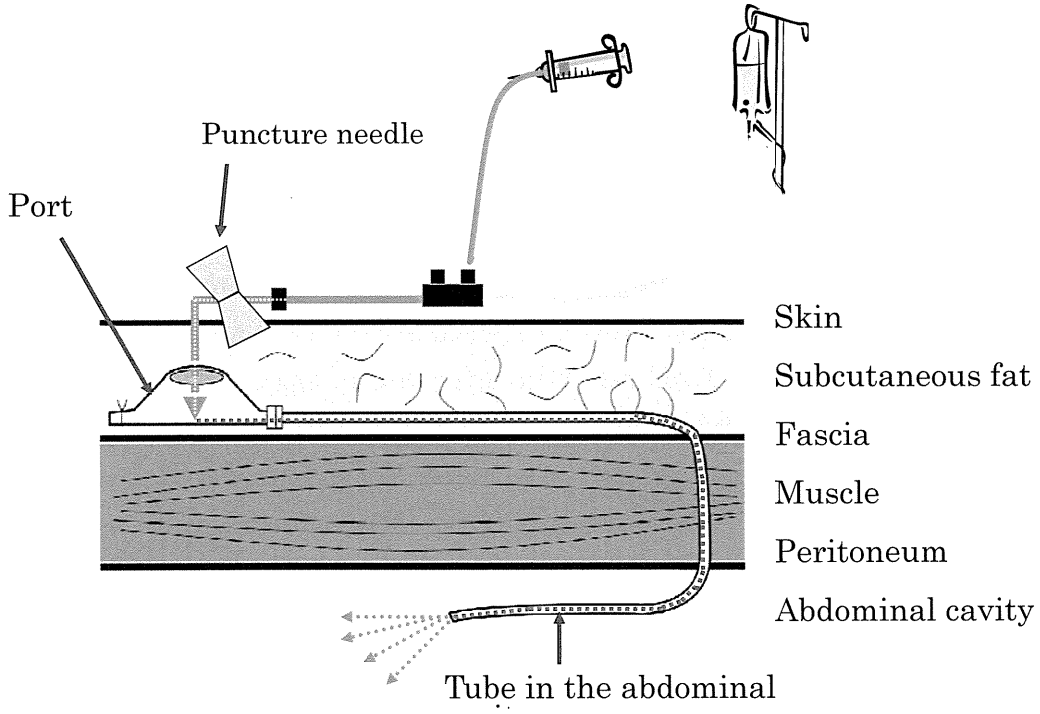
In order to administer anti-cancer drugs into the abdominal cavity, the peritoneal reservoir port becomes necessary. The peritoneal reservoir port is the equipment for administering anti-cancer drugs into your abdomen, and is implanted under the skin of the abdomen (please refer to the figure below). In this figure, the equipment is implanted in the right upper abdomen; however, in actual practice, it will be placed in a location considered optimal for the patient. Some patients may experience some discomfort in the location where the peritoneal reservoir port is implanted. However, the implant does not usually cause pain or impact daily activities such as having a bath. The equipment will be removed from the body if the implanted reservoir does not function properly, cause infections, or if all scheduled study treatment has been completed. Because the implanted equipment usually does not have a special impact on life, there is no need to remove the equipment if you do not wish to have it removed.

Peritoneal reservoir port in the abdomen



A part of the equipment implanted under the skin (the circular part) enables multiple injections. Carboplatin is injected into the abdomen from here.

Carboplatin will travel through the tube and spread to whole of the abdomen. The injected Carboplatin will be naturally absorbed by the body over approximately 24 hours and removed from the abdomen.



Whether Carboplatin is administered intravenously or via the peritoneum will be determined during laparotomy. The reason for this is that the clinical study involves stage II, III, and IV patients, and the stages of the ovarian cancer cannot be diagnosed without laparotomy. The peritoneal reservoir port will be implanted during the surgery only in patients who

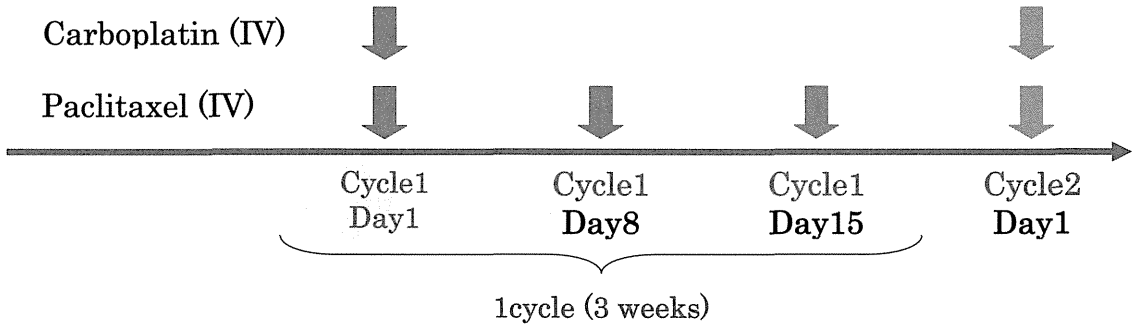
were allocated to peritoneal Carboplatin administration by randomization. Implant of peritoneal reservoir port will not be conducted for patients who are allocated to intravenous carboplatin administration.

In some patient, placement of the IP port may be performed after surgery.

3. Study treatment methods

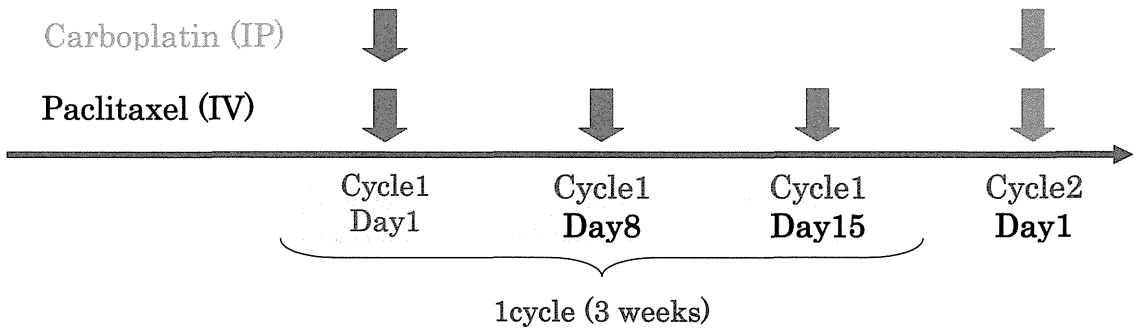
Treatment method (i): For intravenous administration of carboplatin

On day 1, paclitaxel is administered as an intravenous drip over 1 hour, then carboplatin is administered as an intravenous drip. Following this, on days 8 and 15, paclitaxel is administered as an intravenous drip over 1 hour. Three weeks of treatment are set as 1 cycle and this treatment is repeated for 6-8 cycles.



Treatment method (ii): For peritoneal administration of carboplatin

On day 1, paclitaxel is administered as an intravenous drip over 1 hour, and at the same time 1000-1500 mL of normal saline liquid will be administered through the reservoir port (equipment inserted into the abdomen during the surgery). After the intravenous drip of paclitaxel is complete, carboplatin will be administered into the abdominal cavity. The dose of carboplatin is the same as when administered intravenously. Following this, on days 8 and 15, paclitaxel is administered as an intravenous drip over 1 hour. Three weeks of treatment is set as 1 cycle, and this treatment is repeated for 6-8 cycles.



As described above, the only difference between the two treatments is whether carboplatin is administered as an intravenous drip or into the abdominal cavity. Depending on the occurrence of adverse reactions, the dose may be reduced or the interval of administration may be prolonged in the following treatment. If strong adverse reactions appear or the administration interval is excessively large, this treatment may be discontinued.

There are cases where patients experience nausea or allergic reactions. These will be prevented by the use of antiemetics or steroids before paclitaxel administration. Furthermore, if the tumor could not be completely removed in the surgery, another surgery may be performed after 3-5 cycles of chemotherapy. If this is the case, further 1-3 cycles of chemotherapy will be added following the surgery, resulting in a total of 6-8 treatment cycles.

4. What is being investigated in this clinical study?

The first point we want to find out in this study is which group of the patients who received (i) the combination of weekly intravenous infusion of paclitaxel and 3-weekly intravenous infusion of carboplatin, or (ii) the combination of weekly intravenous infusion of paclitaxel and 3-weekly peritoneal administration of carboplatin live longer periods without a progression of a disease of recurrence of cancer.

We will also investigate the survival period of the patients after treatment, the effect of the treatment to reduce the tumor size if tumors remain after surgery, as well as the rates of patients who have completed the treatment as scheduled and the types and severity of adverse reactions. Furthermore, we will investigate the patient's quality of life (QOL) and the cost incurred from treatment.

QOL survey will be conducted before the initial treatment, after 3 cycles of protocol treatment (or 9 weeks after the date of treatment commencement), after 6 cycles of protocol treatment (or 18 weeks after starting treatment), 36 weeks after starting treatment, 60 weeks after starting treatment, and 84 weeks after starting treatment. We ask all patients who participate in this study to fill in the QOL survey. Specifically, you will be handed the survey sheet by the QOL staff of the hospital you are attending, so please answer the questions, then hand it back to the QOL staff.

In this clinical study, the cost involved in the study will be investigated, and compared between the group being administered carboplatin intravenously and the group being administered carboplatin via the peritoneum. Regardless of the group you are allocated in, you will be asked to report the cost you pay at hospitals and pharmacies, as well as other costs such as travelling costs to the hospital.

If you are able to cooperate in this cost study, information such as the type of your insurance and amounts of hospital payments need to be send to the iPocc Trial Coordinating Center for this clinical study. In addition, you will be asked to cooperate in the regular survey on your personal payments such as pharmacies payments and traveling costs to the hospital. These data will be accumulated at the iPocc Trial Coordinating Center (Kitasato University Research Center for Clinical Pharmacology, 5-9-1 Shirokane, Minato-ku, Tokyo, Japan).

Please make your own decision on whether you will participate in the cost study for this clinical study.

If you decide to participate in this study, various examinations and symptom observations will be conducted regularly. This includes physical examination by a doctor, blood tests, urine test, imaging examinations such as CT and MRI, as well as a survey of the quality of life (QOL). All of these examinations are conducted to investigate the effects and safety of these treatments. In regards to examinations other than the QOL survey, these are conducted during normal treatments as required, even if you do not participate in this clinical study. You may find that you will undergo blood tests or imaging examinations slightly more often in the clinical studies, since these examinations are conducted more often in case adverse effects occur. After the completion of the clinical study, long-term follow-up observations need to be conducted regularly, as after the general cancer treatment.

This study is for the patients with epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer in the tissues excised by surgery. For this reason, we will submit a thin slice of this cancer tissue on a slide and specialists of the Central Pathology Committee will once again confirm the diagnosis.

5. If the study is discontinued

If you are unable to continue the study due to adverse reactions or other disorders, your participation in the study will be discontinued. If the study is discontinued due to adverse reactions, regular examinations and observations will be conducted until it disappears. Also, appropriate treatments for the adverse effects will be provided as required. The chemotherapy tumor may not work as expected, and the tumor may grow during the treatment. The study will be discontinued in such cases, and other appropriate treatments will be provided.

Expected adverse reactions

Cancer cells have disordered functions in regulating cell growth and are characteristic in that they have faster growth compared to healthy cells. Anti-cancer cells attack the cancer cells using this characteristic as the target; however, some healthy cells grow fast, and adverse effects occur from the effect of anti-cancer drugs on these cells. Typical examples are the hematopoietic cells in the bone marrow and the cells at the hair root. There is a wide variety on how adverse effects appear for individual patient, and it is impossible to predict beforehand what adverse effects are experienced by each patient.

Therefore, the treatment is carried out carefully while observing the conditions of the patients. The main adverse reactions that are generally expected to occur are as follows:

♦Reduced blood cells, such as white blood cells and neutrophils:
If the decrease of white blood cells (or neutrophils) appears strongly, the patients may be injected with drugs to increase white blood cells (neutrophils) (G-CSF preparation). The decrease in white blood cells (or neutrophils) may accompany fever or result in an increased risk of infections. Please contact immediately if you experience change of physical conditions (especially fever) during the treatment period. We will use antibiotics in case an infection occurs.

♦Anemia or decreased platelets:
If anemia becomes severe, you become more likely to experience a feeling of heaviness, fatigue, and lightheadedness. Also, since platelets have a blood-clotting function, a decrease in the platelets results in bleeding more easily. If this symptom is severe, transfusions may be required.

♦Hair loss:

Although this varies with individuals, some patients may lose so much hair that they need to wear wigs. The hair will grow back after the treatment has ended.

♦Loss of appetite, general malaise, hot flushes, nausea, and vomiting are expected to occur. These symptoms disappear after stopping the medication; however, nausea and vomiting can be relieved using drugs.

♦In addition, changed liver functions and decreased kidney functions may occur.

♦It is known that treatment with anti-cancer drugs increases the risk of developing secondary cancer, such as acute leukemia.

In addition, muscle aches and joint pain may occur as adverse effects of paclitaxel. These adverse reactions can be treated with painkillers. Also, numbness may occur in the tips of the fingers and toes. Chinese medicine with (*Goshajinkigan* and *Shakuyakukanzoutou*) may be used for numbness; however, if these symptoms affect your daily activities, Paclitaxel may be discontinued. These adverse effects are observed relatively often. Furthermore, the following adverse effects may occur, though these have lower incidences: hives, allergic reactions, abnormal pulse such as arrhythmia, diarrhea, stomatitis, changed taste sensation, headache, increased neutral fat in blood, mood changes, skin disorders (if the drug solution leaked from the blood vessels during administration), changes in visual sensation (blurring, etc.), cerebral edema, convulsions, etc. In addition, although the incidence is unknown there is a chance of interstitial pneumonia occurring. Interstitial pneumonia is inflammation of lungs caused by various drugs, and it is often treatment-resistant and may lead to death. We will observe carefully for symptoms such as breathing difficulty and coughs during the study period.

The adverse reactions of carboplatin, which are observed relatively often, are decreased white blood cells and neutrophils, and anemia. Other possible adverse effects are as follows: allergic reactions, loss of appetite, diarrhea, constipation, nausea, abdominal pain, skin rash, changed taste sensation, changed visual sensation, hand/food numbness, convulsion, ringing of the ears, decreased hearing, hearing loss, fever, decreased kidney or liver function, stomatitis, etc. In addition, interstitial pneumonia may occur though the incidence is not high.

As adverse reactions of combination therapy of intravenous paclitaxel and peritoneal carboplatin, abdominal pain may be experienced from the stimulation of inserting drugs into the abdomen. The symptoms can be suppressed using painkillers; however, if the symptoms are severe, the treatment may be changed. Also, though these are very rare, peritonitis or holes in intestinal tract may occur from implanting the peritoneal reservoir port. Appropriate actions will be carried out immediately in such cases. Other possible adverse reactions include those listed before in regards to the individual drugs.

Adverse reactions specific to peritoneal administration include the followings. In order to repeatedly administer the drugs via the abdomen, a device called a reservoir port will be implanted under the skin. This will be implanted only in patients allocated to the peritoneal administration group of this study immediately before the completion of the initial surgery. The technique is not difficult; however, it may occasionally result in hematoma. In addition, the ascites, or biological saline liquid or drugs which have been injected into the abdominal cavity, may flow back into the port. If Carboplatin flows back into the subcutaneous layer or leaks from the port, there may be needed to take actions such as steroid administration, however, such cases becoming serious matters are very rare.

Since reservoir ports are implanted in the subcutaneous fat, the section of implant sticks a little. You may experience discomfort or mild pain; however, these usually subside with time. When inserting injection needles to the port, this is conducted carefully; however, it may cause infection. If it is not appropriate to leave the port inside the body, such as in the case of severe pain in the port location and infection, the port will be removed.

There are cases where the intestinal tract becomes adhered around the catheter at the end of the reservoir port, disabling peritoneal injection. It is extremely rare that surgery is required for adhesion around the catheter; however, peritoneal administration will be discontinued nonetheless. Also, there is a possibility that hole (perforation) will form in the intestines or the sutured sections of vagina from the tip of catheter coming in contact with the location of surgery, but this is rare. If this occurs, peritoneal administration will be discontinued, and if required laparotomy will be conducted to repair the perforated location.

The reservoir port is made of materials that do not cause problems if the device is left in the body permanently in most cases. However, this can be removed after the study treatment. The device is removed usually under

local anesthetic with an incision made on the section of the port. However, if it cannot be removed smoothly or if it is strongly suspected that the catheter is adhered to the intestines, it is expected that a laparotomy must be performed under general anesthetic. Removal of the reservoir port involves relevant costs.

These adverse reactions are those that have been reported up to now, and not all patients will necessarily experience these adverse reactions. Also, due to the nature of the drugs used in this treatment, there is a possibility that unexpected adverse reaction may appear. The treating physician will carefully observe for these adverse reactions and will carry out any possible and appropriate measures when required. If you experience anything abnormal during this treatment, please feel free to consult your treating physician or nurses.

Other treatment options

If you choose not to participate in this clinical study, the following treatment options are available. The standard postsurgical treatment for ovarian cancer is a 3-weekly intravenous administration of paclitaxel and carboplatin. You are able to receive the standard treatment without participating in this clinical study. Other options for drugs include cisplatin and docetaxel, and treatment can be chosen depending on the occurrence of an allergy and other adverse reactions. Radiotherapy is generally not selected for cases such as yours; however, it may be adopted depending on the conditions. Also immunotherapy may also be adopted as a treatment option.

Potencies benefits and disadvantages of participating in this clinical study

It is not known whether your participation in this study will benefit you directly. Your treating physician is expecting that the treatment in this clinical study will suppress the progression and recurrence of cancer without causing strong adverse reactions; however, we cannot promise this will be the case.

There are both advantages and disadvantages to both of the treatments involved in this clinical study. One of the advantages for administering both drugs intravenously may be that it is easier to predict what kind of adverse reactions will appear, since this treatment has been used more. On the

other hand, peritoneal administration may cause more adverse reactions; however, these may be able to be controlled and result in a better therapeutic effect. However, with peritoneal administration, patients are more likely to experience adverse reactions, which almost never occur in intravenous administration (such as abdominal pain or peritonitis) and which may be the potential disadvantageous.

These are only estimates at the "maybe" level, which we consider from the results of small clinical studies and experience from the past. This clinical study is conducted to clarify the balance of advantages and disadvantages in these treatments.

We cannot guarantee you a clear benefit at this stage; however, the information we can obtained from this clinical study on the effects and adverse reactions associated with these treatments will be utilized in the future for the treatment of many patients who have the same disorder as you.

Guidelines which this study complies with

This clinical study is conducted in adherence with the Helsinki Declaration, which sets out the principles for medical ethics. This study also complies with the relevant ethical guidelines for clinical research in the country.

Not agreeing to participation does not result in disadvantage

In regards to your participation in this study, we will ask you to make a decision voluntarily. You will not being disadvantage in future treatments or care even if you do not agree. You may be concerned that the treating physician will be offended or that you may be unable to receive sufficient treatment if you do not agree to participate; however, this is not the case. Even if you choose not to participate in this study, your treating physician will explain other treatment options, so please discuss thoroughly with your treating physician.

Agreement can be cancelled at any time afterwards

You can cancel your participation in this study at any time. Even after the treatment has started, you can cancel participation for any reason (such as not being able to bear the adverse reactions). Please do not hesitate to talk to your treating physician. Even if the clinical study is discontinued, another appropriate treatment will be provided for you.

However, if you are unable to continue the study treatment and specified

visit to the hospital, the previously collected data are to be used up to this time point. Also, if the treatment is discontinued, you need to visit the hospital for follow-up observations on whether the cancer has recurred.

Information regarding the study

Both of the drugs used in this study are already marketed. If new and significant information was obtained during your participation in the study, we will provide you with the information to confirm your continued participation in the study.

The final results of the clinical study will be available after a few years. When the results are finalized, your treating physician will provide you with an explanation on the final results of the clinical study.

Protection of personal information

A part of your medical records will be sent to the iPocc Trial Coordinating Center (Kitasato University Research Center for Clinical Pharmacology, Clinical Trial Coordinating Center: 5-9-1 Shirokane, Minato-ku, Tokyo, Japan). The study staff of the Coordination Center may see the records containing your medical information; however, the reports are do not contain your personal information.

In order to check that this clinical study is being carried out appropriately, the appointed staff, such as auditors and the monitor, may see the records. Alternatively, there may be investigations on the study by representatives of governmental authorities, such as the Minister of Health, Labor and Welfare (MHLW) in Japan. In all of these cases, we will take utmost care in protecting your personal information and privacy.

The results obtained in this study will be used to confirm the safety and effectiveness of the treatments used. We plan to publish the study results will be presented at medical meetings and academic journals. However, please be assured that your personally information (such as your name) will not be published, as the study results will be reported as an aggregate of approximately 654 patients.

In cases of adverse reactions

We will conduct the treatments carefully; however, there is a possibility that health hazards may occur during the study or after study completion in regards to the treatment you have received. You will not be given monetary compensation in principle, as with any other clinical studies investigating

the effects of anti-cancer drugs. However, if any adverse reactions occur, we will provide the appropriate treatment. The fee incurred for such situations will be covered by health insurance with partial out-of-pocket payment from the patient.

This clinical study is covered by clinical trial insurance in Japan. In some cases, if you are injured as a result of faults in the study protocol, which specified procedures for the study, compensation may be covered with this insurance. It is important that you tell your physician, if you feel that you have been injured because of taking in part of the study not only during the study but also after study completion.

Requests for patients participating the study

During the study period, we ask you to cooperate in the required examinations, which are necessary for appropriate evaluation of the treatments, as well as for your safety. Also, if you experience any abnormal physical state, please seek care from your treating physician as soon as possible. If you must attend other hospitals, please advise them that you are participating in a clinical study, and advise your treating physician in this institution that you have seen a doctor outside. Please make sure to tell your treating physician if you are taking any other medications (including over-the-counter drugs and supplements). If you have any questions regarding this clinical study, please do not hesitate to ask you treating physician at any time.

Requests for patients with peritoneal reservoir port implanted

In an extremely rare instance, you may be stopped at metal detectors set up in such locations as airport gates. We recommend that you carry around the diagnosis document, as well as a card indicating you have a peritoneal reservoir port implanted. You will be safe to undergo examinations such as X-ray/MRI/CT while the port is implanted.

Ethical assessment of this clinical study

This clinical study has been thoroughly investigated by many medical professionals. Also, the study is approved by the institutional review board (IRB) as considering the protection of the rights and safety of the patients. The hospital staff involved in the clinical study will also act to protect them. If you have an inquiry regarding patient rights, please contact the details below.

This clinical study is reviewed by:

Name:

Founder:

Address:

Web URL:

The contact details of the investigator for the study are as follows:

Investigator

Name:

Contact (affiliation): (title)

Phone no.:

If you have any complaints related to this study, you can talk to a person who is not directly involved the in the study. Please feel free to contact the person below:

Patient representative

Name of representative staff

Affiliation (title)

Phone no.

Research funds and conflict of interests

This clinical study is founded mainly by the Health Labour Sciences Research Grant from MLW, with research expenses, partially covered by GOTIC (Gynecologic Oncology Trial and Investigation Consortium) and JGOG (Japanese Gynecologic Oncology Group).

At Hospital name:, we check that all personnel directly involved in this study are not in a state where they may personally profit from this study (this is called a conflict of interest). Also, the other members of the study team at other institution as well as at iPocc trial Coordinating Center have undergone assessments on conflict of interests related to this study by concerned party.

Study information in public

This study is registered in the clinical trial register UMIN (University Hospital Medical Information Network) in Japanese http://www.umin.ac.jp/ctr/index-j.htm, as well as clinical.gov in English http://clinicaltrials.gov/ for the purpose of making the study information available to the public. Information such as methods, progress, and results

of the study can be obtained by anyone via the internet.

Final note

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If anything is unclear, please do not hesitate to ask your treating physician at any time.

If after careful consideration you decide to participate in this clinical study, please sign and date the consent form on the next page and hand it to the treating physician. We will make a copy of the consent form for you to keep.

Patient Consent Form

To the director of (hospital name)_____

Date of explanation (DD/MM/YYYY)
Physician who provided the information
Name of Department
Name of physician (autograph)

I have been given a copy of all XX (*insert total number of pages*) pages of this form. I have read the study information including QOL and cost investigation or it has been read it to me. I understand the information and have had my questions answered. I agree to take part in this study, "**A randomized phase II/ III trial of Intravenous (IV) Paclitaxel weekly plus IV Carboplatin once every 3 weeks versus IV Paclitaxel weekly plus intraperitoneal (IP) Carboplatin once every 3 weeks in women with epithelial ovarian, fallopian tube or primary peritoneal cancer**"

- □ **I will participate in the study including QOL and cost investigation**
- □ **I will participate in the study except cost investigation**

_____

Patient name (signature) Date

_____

Name of legal representative[when necessary] Date
Relationship with the patient
* Fill in only when required (signature)

I confirm that I have provided sufficient explanation on the study above, that consent has been obtained from the patient, and that I have handed a copy of the patient information and the consent form.

_____

Treating physician (signature) Date

同意説明文書

マレーシア語版

IZIN TERMAKLUM SUBJEK

Nombor Kajian: GOTIC-001 / JGOG3019

Nama Kajian: **Kajian iPOCC** (Terapi IntraPeritoneum untuk Barah Ovari dengan Karboplatin (Carboplatin))
Fasa Rambang II / III Ujian Intravena (IV) Paclitaxel Secara Mingguan Ditambah dengan IV Karboplatin (Carboplatin) sekali setiap 3 minggu Berbanding dengan IV Paclitaxel Secara Mingguan Ditambah dengan IntraPeritoneum (IP) Karboplatin (Carboplatin) sekali setiap 3 minggu dalam wanita yang menghidapi Barah Epitelium Ovari, Barah Tiub Fallopio atau Barah Peritoneal Utama.

Doktor Kajian: Dr Lim Sheow Lei
Jabatan Ginekologi - Onkologi
Hospital Wanita dan Kanak-kanak KK
100 Bukit Timah Road, Singapura 229899
No. Telefon: (65) 6225 5554

NAMA SUBJEK (SEPERTI DI DALAM NRIC): _____

Pendahuluan:

Anda diundang untuk mengambil bahagian dalam satu kaji selidik, kajian iPOCC. Sebelum anda memutuskan untuk turut serta, adalah penting untuk anda memahami mengapa kajian ini sedang dijalankan dan apakah yang akan terlibat.

Borang ini digelar "izin termaklum". Ia menyediakan maklumat tentang kajian ini dalam usaha untuk membantu anda membuat keputusan jika anda ingin mengambil bahagian dalam kajian ini. Sila baca borang ini dengan berhati-hati dan tanyakan apa-apa soalan yang anda miliki mengenai kajian ini supaya anda dapat membuat keputusan bermaklumat mengenai penyertaan anda. Doktor kajian atau jururawat kajian juga akan membincangkan maklumat di dalam borang izin ini bersama anda secara terperinci dan menjawab sebarang soalan-soalan yang anda mungkin ada berkaitan kajian ini. Anda boleh membawa pulang salinan tidak bertandatangan borang ini untuk membuat pertimbangan sebelum membuat keputusan anda. Sila ambil seberapa banyak masa yang perlu kerana anda perlu memutuskan sama ada anda ingin mengambil bahagian dan sila bincangkan tentang penyertaan anda bersama keluarga, rakan-rakan, atau doktor anda, jika anda mahu.

Jika selepas membaca dokumen ini, anda berminat untuk mengambil bahagian dalam kaji selidik ini, anda akan diminta untuk menandatangani borang izin termaklum. Anda akan menerima satu salinan borang ini untuk disimpan. Doktor kajian akan mengesahkan jika anda memenuhi syarat–syarat perubatan yang tertentu sebelum meneruskan kajian. Semua ini akan diterangkan secara terperinci kepada anda.

Penyertaan anda dalam kaji selidik ini adalah secara sukarela sepenuhnya. Jika anda memutuskan untuk tidak menyertai kajian ini, anda tidak akan kehilangan sebarang perkhidmatan penjagaan kesihatan yang anda telah berhak untuk menerima. Melibatkan diri dalam kajian ini tidak akan menggantikan penjagaan perubatan biasa anda.