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 746 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: Saitama Medical University International Medical Center IRB
Founder: Director of a hospital Isamu Koyama
Address: 1397-1 Yamane,Hidaka-City Saitama 350-1298 Japan
Web URL: http://www.saitama-med.ac.jp/kokusai/

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

Investigator

Name: Keiichi Fujiwara
Contact (affiliation): Gynecologic Oncology (title) Professor
Phone no.: 042-984-4111

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: Masayuki Ishii
Affiliation: Clinical Trials Support Center (title) Administrator
Phone no. 042-984-4523

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 Saitama Medical University International Medical Center, 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 Saitama Medical University International Medical Center ,

Date of explanation (D /M /Y)
Physician who provided the information
Name of Department Gynecologic Oncology
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

同意説明文書例

中国語版

iPocc 试验

卵巢癌卡铂腹腔内治疗
（IntraPeritoneal therapy for Ovarian Cancer with Carboplatin）

GOTIC-001 / JGOG3019

一项让罹患上皮性卵巢癌、输卵管癌或原发性腹膜癌的女性每周通过静脉（IV）接获紫杉醇（PACLITAXEL）加每三周通过静脉接获卡铂（CARBOPLATIN）相对于每周通过静脉接获紫杉醇（PACLITAXEL）加每三周通过腹腔（IP）接获卡铂（CARBOPLATIN）的随机化、第 II/ III 期研究

患者说明书

简介

我们在（医院名称：）_____进行称为“临床试验”的试验性治疗，以便为您提供最新的治疗方法。“临床试验”是指在患者的配合之下进行的研究，以查明新的治疗方法或药物是否能有效地对抗某些疾病。通过临床试验获取资料与数据对于疾病治疗的发展非常重要。我们目前所使用的所有药物和治疗都是过去累积的临床试验的成果。

在临床试验里，研究人员会在取得患者的同意后，严格按照研究计划对新疗法的效用和安全性进行调查。我们现在邀请您参与的临床研究所调查的内容是，若将结合抗癌药物治疗的两种药物当中的其中一种（已用于治疗卵巢癌患者的药物）的给药方式从静脉给药改为腹腔给药，哪一种给药方式是有效的。目前还不知道这些给药方式当中，哪一种比较有效。

这是一项国际性的试验，妇科癌症协作组（GCIG，Gynecologic Cancer Intergroup）。在日本，这项试验是由专门进行妇科癌症研究的研究机构 GOTIC （妇科肿瘤学试验与调查集团，Gynecologic Oncology Trial and Investigation Consortium）与 JGOG （日本妇科肿瘤学集团，Japanese Gynecologic Oncology Group）联合执行的。

（医院名称：）_____（部门名称：）_____ 作为获准参与的研究中心，目前正在开展这项临床试验。

这项临床研究称为 iPocc 研究。

关于参与本研究

我们将对本临床研究进行说明，而由于您的情况符合参与本临床研究的患者的条件，我们恳请您考虑参与本研究。您可以自行决定参与或不参与本临床研究。您可以征询其他专业医务人员的意见。您决定不参与本研究并不会影响您与您的主治医生之间的关系，也不会对您造成不利，例如使您无法接受治疗。此外，您也可以在研究开始后随时取消在本临床研究的参与。

关于同意

在您的主治医生向您充分说明有关本临床研究而且您充分了解有关说明之后，请自行决定是否要参与本研究。您可以和您的家人和朋友讨论。请花些时间考虑此事。

本临床研究的目的

本临床研究涉及两种治疗方法（两种治疗方法都使用相同的药物，不过采用静脉或腹腔两种不同的给药方式），使用两种分别称为紫杉醇（paclitaxel）和卡铂（carboplatin）药物，目的是要比较这两种治疗方法对于被诊断患有第

II、III 和第 IV 期上皮卵巢癌；输卵管癌，或原发性腹膜癌的患者的效用和不良作用，以便调查哪一种治疗方法对患者比较好。下文将说明研究的详情。

以下说明适用于卵巢癌患者，不过，上皮卵巢癌、输卵管癌和原发性腹膜癌在性质上都非常类似。腹膜癌发生在腹膜内，而输卵管癌出现在输卵管的上皮组织，不过，这些病症和上皮卵巢癌的病因是相同的。已知对卵巢癌有效的化学治疗（使用抗癌药物的疗法）也对这些类型的癌症有效。

如果您被诊断患有输卵管癌或原发性腹膜癌，请在阅读本说明书时用“输卵管癌”或“原发性腹膜癌”取代“卵巢癌”这个词汇。

预计参与研究的患者人数以及预定的研究期限

本临床研究于 2010 年 5 月在日本展开。大约 746 名情况与您相同的患者将参与研究。研究的治疗期因人而异；不过，大约为 5 至 7 个月。完成治疗后另有大约 3 年的跟进期，以便定期观察患者的情况。

本临床研究的背景

由于诊断早期卵巢癌的方法尚未确立，其症状亦不容易被发现，60%或以上的患者在被诊断患有此病症时，癌症已经扩散至腹部。因此，卵巢癌被认为是相对难以治疗的癌症之一。

晚期卵巢癌的标准治疗（被认为是目前最佳的治疗方法）是通过手术去除肿瘤，然后进行抗癌药物治疗。通常会使用两种药物，即紫杉醇（paclitaxel）和卡铂（carboplatin），每 3 至 4 周通过静脉输注给药，大约施与 6 次。然而在现实情况里，超过半数的患者在接受此治疗后癌症复发，因而迫切需要研发一种更有效的治疗方法。

一项 2008 年在日本进行的临床研究对（i）每 3 周通过静脉滴注施与紫杉醇（paclitaxel）和卡铂（carboplatin）的传统治疗，和（ii）每周通过静脉施与相对少量的紫杉醇（paclitaxel）和每 3 周通过静脉滴注施与卡铂（carboplatin）的新疗法进行了比较，结果显示接获（ii）新疗法的患者的预后有所改进。这项发现引起了全球性的关注。

卵巢癌常扩散到整个腹腔（腹部）。为此，数十年前便研发出在腹腔施与抗癌药物的给药方式。此方法预计会极为有效，因为与通过静脉给药相比，这种方法能将更高剂量的抗癌药物直接施与肿瘤部位。此外通过静脉给药时，抗癌药物需要在扩散至全身后才会发挥功效，相比之下，腹腔给药的方法所引起的不良反应预计会较轻。

在过去的大约 10 年里，欧洲和美国的众多卵巢癌患者参与了许多有关腹腔施与抗癌药物的临床研究。结果显示，和静脉给药相比，接受腹腔施与抗癌药物治疗的卵巢癌患者的死亡风险降低了 21.6%。这项发现引起了广泛的关注。根据到目前为止所进行的临床研究的结果，被认为最有效的治疗方法是（iii）每 3 周通过静脉施与紫杉醇（paclitaxel）和每 3 周通过腹腔施与顺铂（cisplatin）（和卡铂（carboplatin）同组的铂类药剂）和紫杉醇（paclitaxel）。不过，此治疗方法与恶心、呕吐或腹痛等强烈的不良反应有关，因此，目前正在研究不良反应较少的治疗方法。在最新接受研究的治疗方法当中，静脉施与紫杉醇（paclitaxel）和腹腔施与卡铂（carboplatin）的结合疗法是备受看好的治疗方法之一。日本方面已对此疗法进行了一些小规模的临床研究，并取得了令人满意的结果，不良作用的发生率也较低。不过，目前还不知道静脉给药或腹腔给药中哪一种的效用更佳。

因此，为了制定一个更有效且不良反应较少的化疗方法，我们策划了这项临床研究来比较以下的治疗方法：

治疗方法 I:

每周静脉滴注施与相对少量的紫杉醇（paclitaxel），结合每 3 周静脉滴注施与卡铂（carboplatin）

治疗方法 II:

每周静脉滴注施与相对少量的紫杉醇（paclitaxel），结合每 3 周腹腔施与卡铂（carboplatin）

有关本临床研究的具体详情

1. 所使用的药物

本临床研究的患者将接受紫杉醇（paclitaxel）和卡铂（carboplatin）两种药物治疗，这两种药物都是世界各地广泛用于治疗卵巢癌的药物。这些药物也被广泛用于治疗其他类型的癌症。

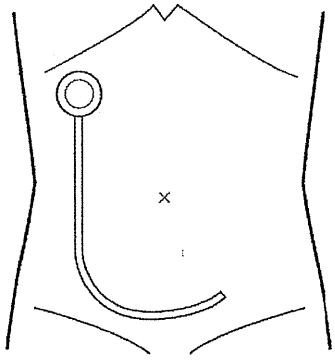
2. 开始研究治疗之前的要求和程序

如果您同意参与研究，我们会在手术前进行例如血液检测和心电图（ECG）等检查，以确定您目前的情况是否适合参与本研究。在某些情况下，我们可能采用您同意参与本研究之前所进行的检查的结果。如果我们从检查结果中发现您不适合参与本研究，即使您已经同意参与研究，您的参与也将被取消。如果手术结果显示您不适合参与本研究，我们也会以同样的方式处理。在这种情况下，您的主治医生会向您解释被认为最适合您的其他治疗方法。

如果您参与本研究，必须在手术进行时（或之后）决定是要通过静脉还是腹部施与卡铂（carboplatin）。您所接获的治疗并非由您或您的主治医生决定，而是在一所第三方机构（北里大学临床药理研究中心，临床试验协调中心： iPocc 试验中心， 5-9-1 Shirokane, Minato-ku, 日本东京）使用电脑以中立的方式来分配（称为“随机化”），以避免任何偏颇。进行分配时，各治疗组的患者的情况（病期、肿瘤体积等）会尽量保持一致，以便对这两种治疗方法进行比较。您可能会问为何患者或主治医生不能决定所采用的治疗方法；其实，全世界的临床研究都采用这种分配方法作为研究哪些治疗最有效或有利的最佳方法。

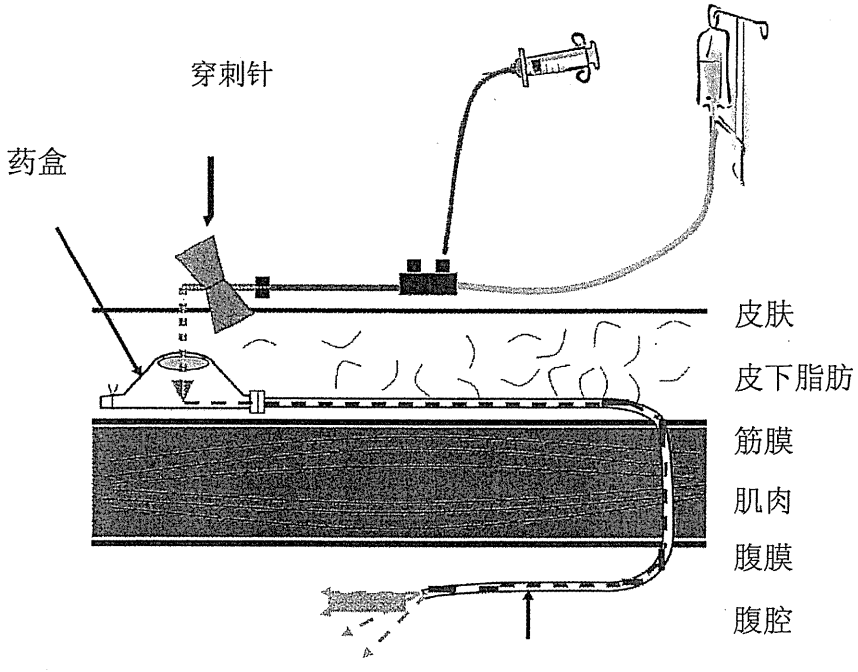
要在腹腔内施与抗癌药物，就必须装置腹膜药盒。腹膜药盒是一种被植入腹部皮下（请见下图），以便在您的腹部施与抗癌药物的器具。如图中所示，器具被植入右上腹，不过在实际操作中，会把器具放置在被认为最适合患者的部位。一些患者可能会感到植入腹膜药盒的部位有些不适。不过，被植入的药盒通常不会造成疼痛或影响日常活动（例如洗澡）。如果植入的药盒没有正常运作、造成感染或所有的预定研究治疗都已完成，便会从体内取出器具。由于植入的器具通常不会对生活有任何特别的影响，如果您不想，也可以不必取出器具。

腹部内的腹膜药盒



部分器具植入皮下（圆圈部分）以便进行多次注射。从这里把卡铂（carboplatin）注射入腹部。

卡铂（carboplatin）会通过导管扩散至整个腹部。注射入体内的卡铂（carboplatin）会在大约24小时里被人体自然吸收并排出腹部。



腹内导管

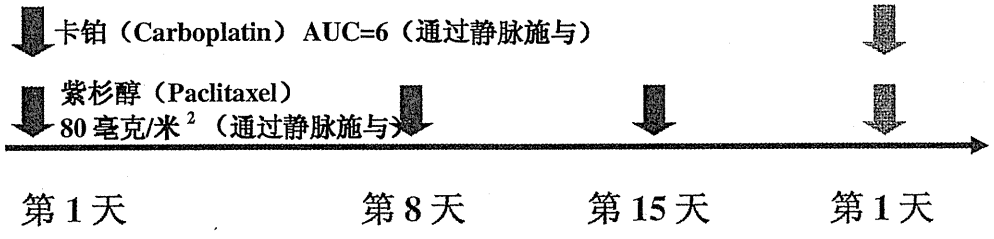
是要通过静脉还是腹腔对患者施与卡铂（carboplatin），将在开腹手术时决定。这是因为本临床研究有第II、III和IV期的患者参与，而必须进行开腹手术方能诊断卵巢癌的病期。唯有在随机化程序时被分配通过腹膜接获卡铂（carboplatin）的患者才会在手术时被植入腹膜药盒。那些被分配通过静脉接获卡铂（carboplatin）的患者则不会被植入腹膜药盒。

一些患者可能会在手术后才装置腹膜药盒。

3. 研究治疗方法

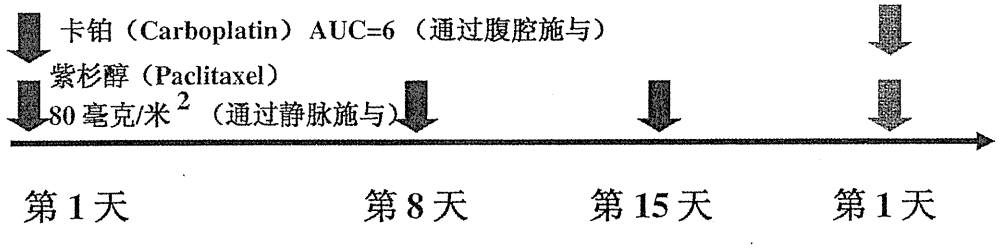
治疗方法（i）： **<u>通过静脉施与</u>卡铂（carboplatin）**

第 1 天，通过 1 个小时的静脉滴注施与紫杉醇（paclitaxel），接着通过静脉滴注施与卡铂（carboplatin）。其后在第 8 和第 15 天，通过 1 个小时的静脉滴注施与紫杉醇（paclitaxel）。三周的治疗定为 1 个疗程，而此治疗将重复进行 6 至 8 个疗程。



治疗方法（ii）： **<u>通过腹腔施与</u>卡铂（carboplatin）**

第 1 天，通过 1 个小时的静脉滴注施与紫杉醇（paclitaxel），同时透过药盒（手术时放置在腹内的器具）施与 1000 至 1500 毫升的生理盐水。完成紫杉醇（paclitaxel）静脉滴注后，将通过腹腔施与卡铂（carboplatin）。卡铂（carboplatin）的剂量和通过静脉施与时的剂量相同。其后在第 8 和第 15 天，通过 1 个小时的静脉滴注施与紫杉醇（paclitaxel）。三周的治疗定为 1 个疗程，而此治疗将重复进行 6 至 8 个疗程。



如上所述，两种治疗方法的唯一区别是卡铂（carboplatin）的施与是通过静脉滴注还是腹腔进行。视不良反应的发生情况而定，接下来的治疗可能会减少药物的剂量或延长两次给药之间的间隔时间。如果出现强烈的不良反应或给药时间相隔太久，可能会中止有关的治疗。

曾有患者出现恶心或过敏反应的情况，因此研究人员会在施与紫杉醇（paclitaxel）之前让患者使用止吐药或类固醇来加以避免。此外，若手术无法完全去除肿瘤，则可在 3 至 5 个疗程的化疗后进行另一次手术。在这种情况下，会在手术后增添 1 至 3 个疗程的化疗，使疗程总数达到 6 至 8 个。

4. 这项临床研究调查的内容是什么？

我们希望从这项研究中得知的第一点是，在接获（i）每周通过静脉输注紫杉醇（paclitaxel）和每 3 周通过静脉输注卡铂（carboplatin）的结合治疗，和（ii）每周通过静脉输注紫杉醇（paclitaxel）和每 3 周通过腹腔施与卡铂（carboplatin）的结合治疗的两组患者当中，哪一组患者存活期较长且没有出现癌症复发的病症恶化的情况。

我们也会调查患者在接受治疗后的存活期、治疗对于缩小肿瘤的作用（如果手术后肿瘤仍然存在），以及按预定计划完成治疗的患者比率和不良反应的类型及严重程度。此外，我们也会调查患者的生活质量（QOL）和治疗所招致的费用。

我们会在首次治疗之前、完成研究治疗的 3 个疗程后（或开始治疗之日的 9 周后）、完成研究治疗的 6 个疗程后（或开始治疗的 18 周后）、开始治疗的 36 周后、开始治疗的 60 周后，以及开始治疗的 84 周后进行“生活质量”（QOL）问卷调查。我们会请所有参与本研究的患者填写 QOL 问卷。具体来说，您参与研究的医院的 QOL 工作人员会把调查表交给您，请回答上面的问题，然后再把问卷交还给 QOL 工作人员。

本临床研究将调查研究所涉及的费用，并在通过静脉施与卡铂（carboplatin）的组别和通过腹膜施与卡铂（carboplatin）的组别之间进行比较。无论您被分配到哪一组，我们都会请您汇报您在医院和药房所支付的费用，以及其他费用（例如前往医院的交通费）。

如果您能够配合这项费用调查，我们需要把一些例如您的保险类型和支付医院的金额等资料送到本临床研究的 iPocc 试验协调中心。此外，我们也需要您配合开展有关您的个人付款（例如支付药方的费用和前往医院的交通费）的常规调查。这些数据将储存于 iPocc 试验协调中心（北里大学临床药理研究中心，临床试验协调中心：5-9-1 Shirokane, Minato-ku, 日本东京）。

请自行决定是否要参与这项临床研究的费用调查。