

August 12, 2023

Request for Participation and Cooperation in the Examination

[Trial Name: Prospective Randomized Comparative Trial on Indocyanine Green-Positive and Negative Staining in Laparoscopic liver subsegmentectomy and segmentectomy]

1. Purpose of the Trial

The purpose of this trial is to investigate which method, either the positive staining method using a reagent called indocyanine green injected into the portal vein along the blood flow during anatomical liver resection or the negative staining method injecting the reagent into the systemic circulation through the arm or other blood vessels, provides a higher accuracy in determining the extent of the liver that should be resected.

2. Trial Method and Duration Subjects

Patients who are scheduled to undergo laparoscopic subsegmentectomy or segmentectomy for primary or metastatic liver cancer at research institutions from the approval of the head of the institution until December 2024, and meet the following conditions:

- I. Individuals aged 18 years or older at the time of consent acquisition
- II. Individuals with preserved liver function
- III. Individuals who consent to participate

Method: If the subjects meet the inclusion criteria, they will undergo surgery to

determine the extent of the liver to be resected using either the indocyanine green-positive staining method or the negative staining method during liver resection. Patients cannot choose between the positive and negative staining methods, and at present, it is not known which method is superior. However, there is generally no disadvantage to patients as a result of this choice.

We plan to recruit a total of 50 patients for this study.

3. Expected Effects and Risks

This study is a prospective registration study conducted within routine insurance medical care. Therefore, we consider the risk of participating in this study to be low. However, in the unlikely event of any health damage, the physicians will provide appropriate examination and treatment. Since this study uses already commercially available drugs within their indications, the treatment of health damage caused by these drugs will be covered by the patients' health insurance, similar to regular medical care. In the event that health damage eligible for compensation occurs, the patient will be able to claim compensation through the Pharmaceutical and Medical Device Act's compensation system for health damage caused by pharmaceutical products.

4. No Disadvantages for Not Agreeing to Participate in the Trial

It is entirely your decision whether or not to cooperate in this trial. Even if you choose not to participate, there will be no disadvantages whatsoever. You will receive the best available treatment using existing drugs and therapies, and there will be no disadvantages in your future treatments.

5. Ability to Withdraw Consent to Participate in the Trial at Any Time

After consenting to participate in this trial, or even during the course of participation, you have the right to withdraw your participation at any time.

6. Costs Related to the Trial

All medical procedures will be conducted within the scope of insurance coverage, so there will be no increase in personal financial burden as a result of participating in this trial.

7. Other Necessary Matters Regarding Protection of Human Rights

Your participation in this research study is voluntary, and your feelings and preferences will be respected. There is no need to worry about the disclosure of your name or privacy to external parties. If you have any questions or concerns regarding the study or medication, please feel free to raise them at any time. Furthermore, the confidentiality of your personal information, such as your name and medical condition, will be strictly protected.

8. Publication of Trial Results

The trial results may be presented and published in academic conferences, papers, etc., for the purpose of benefiting future treatments. However, we assure you once again that the confidentiality of your personal information, including your name, will be strictly maintained.

[Contact Information at Our Hospital]

Department of Surgery, Ageo Central General Hospital,

Taiga Wakabayashi

TEL: 048-773-1111 (Main Line)

Physician or other staff who provided the explanation:

Consent Form

I have received an explanation regarding the trial named "Prospective Randomized Comparative Trial on Indocyanine Green-Positive and Negative Staining Methods in Laparoscopic Subsegmental Liver Resection" using the attached explanatory document, and I fully understand the methods, risks, handling of trial results, etc. Therefore, of my own free will, I consent to participate in the trial.

Please mark a check (✓) in the box to indicate your understanding for the following items (you may check orally):

- ☐ Purpose of the trial
- ☐ Trial method and duration
- ☐ Expected effects and risks
- ☐ No disadvantages for not agreeing to participate in the trial
- ☐ Ability to withdraw consent to participate at any time
- ☐ Costs related to the trial
- ☐ Other necessary matters regarding protection of human rights
- ☐ Publication of trial results

Date:

Signature:

Date of Explanation:

Signature of Explaining Physician: