Subject Instructions

This explanatory note has been prepared to provide you with information about this clinical study. You should read the instructions and consent form carefully before deciding whether to participate in this study or not. It is important that you understand why this research is being done and what it does. It is up to you to decide to participate in this study. In all matters, you can decide to participate or to give up at your own discretion. Also, you will not be penalized for any of your decisions. If you wish to participate in the clinical trial after reading the explanation below, only those who have voluntarily signed and consented will proceed with the clinical trial. Your signature means that you have been informed of the study and the risks, and your signature on this document means that you (or your legal representative) wish to participate in this study.

1. Study title

Comparison of success rate and complication between conventional versus new anchoring device using paracentesis for cirrhotic patients with ascites

2. Principal Investigator and Implementing Institution of this Study

Principal inverstigator : Sang gyune Kim (Collaborator Yung seok Kim, Jung ju You, So hyeon Jeon)

Implementing instituition : Soon chun hyang UH, Bucheon

Address : 170 Jomaru-ro Soon chun hyang UH, Bucheon liver clinic, Gyeonggi-do, Bucheon city

3. Purpose of clinical research

The purpose of this study was to compare the success rate of ascites puncture between conventional method and kara-hoc in patients with cirrhosis with refractory ascites.

4. Background of clinical research

As cirrhosis progresses, ascites develops, which gradually leads to respiratory distress and abdominal distension. Most patients can reduce ascites by using a diuretics, but when the ascites does not decrease even after a sufficient amount of the diuretics used, or when it is impossible to use a diuretic due to renal dysfunction, it is called intractable ascites. In this case, therapeutic ascites puncture is performed in which the abdominal wall puncutured with an needle and the ascites accumulated in the abdominal cavity is directly drained to the outside. Conventional therapeutic ascites puncture uses a vascular catheter to pierce the abdominal wall. Because there is no special fixing device and it has to be fixed to the abdominal wall using gauze and tape, the catheter is often pulled out during ascites drainage, and a re-puncture may be required because the drainage is not sufficient as needed. The Karahoc set is a catheter set with a device to fix the catheter to the abdominal wall after puncture to compensate for the instability of catheter maintenance during ascites drainage in the conventional method. With the new instrument, it is expected that a sufficient amount of ascites can be successfully drained without recapitulation than with the old method.

5. Study Participation Criteria

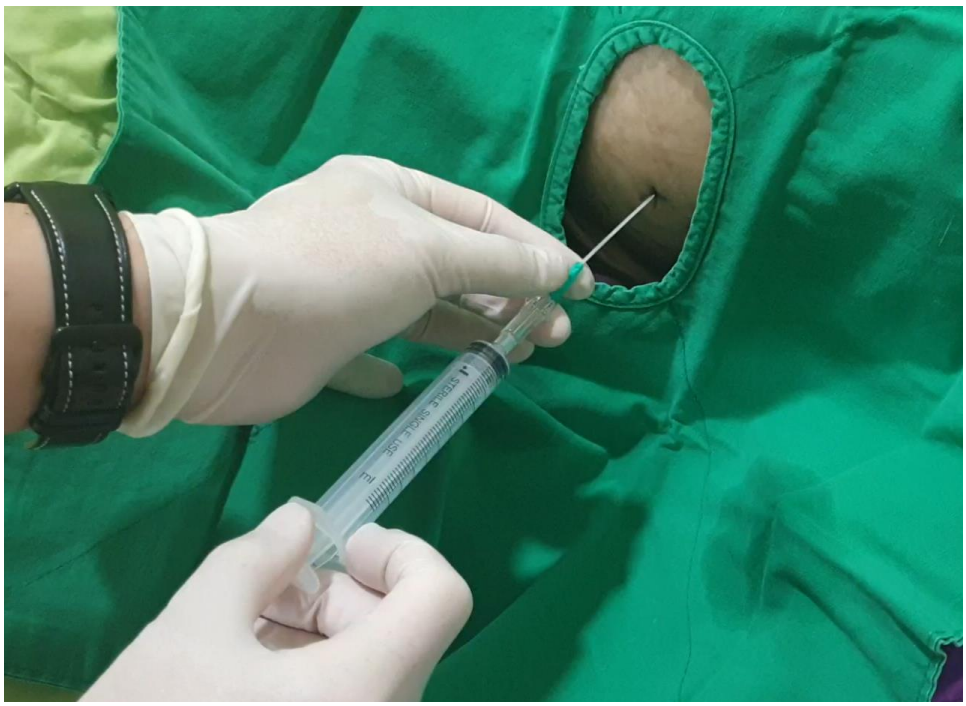
To participate in this study you should be adult men and women over the age of 19, with pathological or clinical diagnosis of cirrhosis and there is grades 2 or higher ascites which required therapeutic paracentesis. The expected number of participants in this study is 80. However, if you have ascites due to a malignant tumor, have a high risk of bleeding, have serious complications such as hepatic encephalopathy or hepatorenal syndrome, if you can control ascites with a diuretic, or if you are pregnant, you will not participate in the study.

6. Types of medical devices used in this study

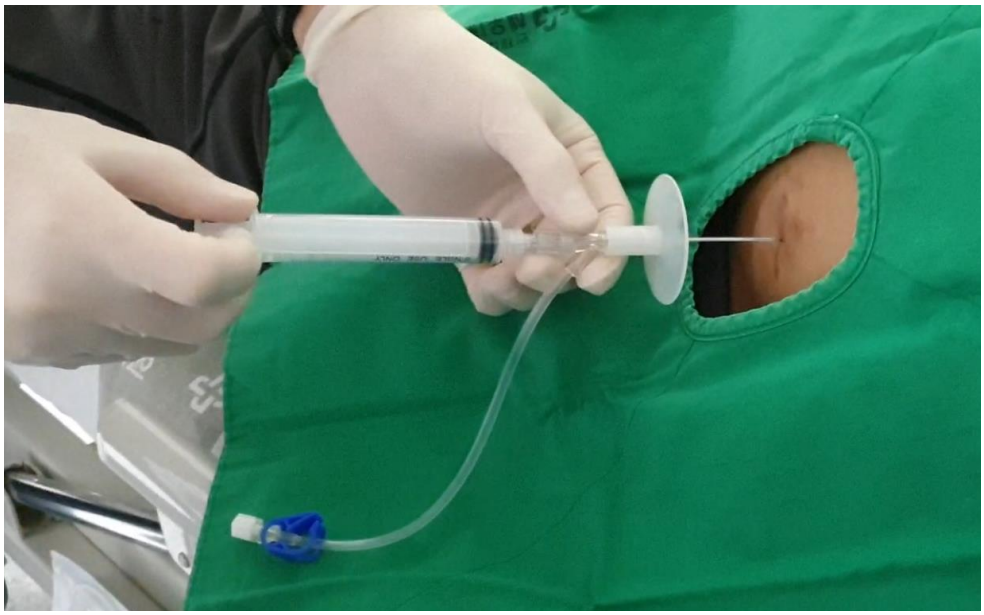
The medical devices used in this study are as follows, and are currently being used in hospitals with permission from the Ministry of Food and Drug Safety.

Product Name: Kara Hoc Set Item name: Universal infusion and drainage tube catheter Components: puncture needle, drainage catheter, syringe, drainage bag, fixed support Purpose of use: After assembling a disposable puncture needle and a drainage tube catheter, it is punctured into the body cavity to collect and drain body fluids to evaluate the living conditions. Pharmaceutical company: Dalim Yanghaeng Co., Ltd.

[Figure 1] Ascites puncture using an angiocatheter



[Figure 2] Ascites puncture using Karahoc



7. What kind of treatment will be provided if I participate in this study?

During the outpatient or hospitalization period, if it is determined that two or more therapeutic ascites punctures are necessary according to the judgment of the attending physician, the procedure will be performed once with a vascular catheter and again with a Karahoc set regardless of the order. If a predetermined amount of ascites is obtained after puncture, the catheter is removed and the procedure is terminated by dressing. A procedure is considered successful when ascites has drained more than 3 L using each instrument, and patient and operator satisfaction is investigated.

8. How will ascites puncture be done if I am not participating in this study?

If you do not participate in this study, you will receive a puncture by choosing one of the existing angiocatheters or Karahoc sets by your doctor's discretion.

9. Complications of medical devices used in this study

The puncture needle of the Karahoc set uses the same formulation as the existing angiocatheter. Therefore, side effects such as hematoma, bleeding, and intestinal perforation may occur after puncture, but it is considered to be the same as the general complications of ascites puncture using a conventional angiocatheter. If you have any questions about any side effects or risk factors that may occur while participating in the study, please contact the researcher in charge immediately.

10. Protection of Confidentiality of Research Records

Information obtained from this study will be given only to the researcher. Your medical record and your signed consent form can only be viewed by researchers and research team members for research purposes. Records that identify you will be kept confidential, and health information will be provided with your full name hidden, so there is no data to know where you live or who you are. Also, even when the results of clinical research are published, your personal information will be kept confidential. You may revoke your consent at any time by notifying the Investigator, in which case the Investigator will no longer be able to use your medical information..

11. Information on compensation for expenses related to participation in this study

If you participate in the research, the Karahoc set will be provided by Darim Yanghaeng Co., Ltd.

12. Measures for subject safety protection and subject compensation for damage

n this study, the investigator will comply with the relevant laws and regulations, and strictly follow the relevant literature, recommendations, and suggestions to conduct clinical trials, and immediate medical management will be made for complications that occurred during the course of this study. However, since the puncture needle of the Karahoc set uses the same formulation as the vascular catheter, common complications that may occur during the puncture process will be treated in the field of daily care. If it is not a common complication, damage caused by this clinical trial will be compensated through the insurance company subscribed by the clinical investigator in accordance with the 'Rules for Compensation for Adverse Event Damage'.

13. Treatment and treatment of subjects after clinical trials

This clinical trial will be terminated by double puncture, and after that, the investigator (physician) will guide you to receive continuous treatment and treatment based on sound medical judgment.

14. Subject Compliance

If you are participating in this study, if you have had any specific symptoms or complications related to ascites puncture in the past, or if you have had a bleeding tendency, please provide information to the investigator in advance so that the risk associated with puncture can be accurately assessed.

15. Criteria and Rules for Discontinuing Treatment of Subjects

Patients have the right to withdraw from study participation at any time and for any reasonThe Investigator reserves the right to withdraw a patient from the trial for poor visit compliance, administrative or other reasons, and the decision to withdraw a patient from the trial is at the

Investigator's discretion. Discontinuation of the study should only be made in accordance with the criteria defined in the protocol or for safety reasons. Patients who were dropped out of this study or whose treatment was discontinued will receive appropriate treatment from their attending physician according to the individual patient's condition.

16. Miscellaneous

1) Your participation in this study may be terminated at any time without your consent by the principal investigator for the following reasons.

- When the examiner determines that it is necessary to stop the test for your health and safety

- When you did not follow the guidelines of the study

- When the research team decides to discontinue the study, or for administrative reasons

2) If you experience any adverse reaction or impairment that may be related to this study, or if you have an unscheduled visit for medical treatment for any reason, In this case, please contact Heo Nae-yoon (051-797-0200), the principal investigator of this clinical trial. If you have any questions about your rights as a participant, please call the Clinical Trial Review Committee (051-797-2747) of this hospital.

3) Other matters necessary for the safety and protection of subjects: This study is conducted according to the clinical trial protocol approved by the clinical trial review committee after sufficiently reviewing the ethical and legal requirements of this study. In addition, throughout the course of the trial, the fundamental spirit of the Declaration of Helsinki, a guideline for doctors in clinical research and KGCP (Medical Clinical Trial Management Standard), will be observed. If new information that may affect your participation in the study is obtained during this study, the researcher will provide you with the information through an appropriate method, If your human rights are violated during this study, you will be notified to the clinical trial review committee or health authorities.

Subject informed consent

*** Research project name : Comparison of success rate and complication between conventional versus new anchoring device using paracentesis for cirrhotic patients with ascites**

Please read the text below and check the box if you fully understand the content..

☐ I have read the subject's explanation and consent form and fully understand the contents.

☐ I listened to the detailed explanation from the doctor in charge, asked questions if I had any questions, and received appropriate answers.

☐ I voluntarily participate in this study.

☐ I authorize the use and sharing of my health information as described in this consent form.

☐ I may refuse or stop participating in the clinical research at any time during the clinical research period. I also understand that there will be no disadvantage on me if I stop participating in this study.

☐ I request to participate in the clinical study according to my free will and receive a copy of the consent form.

Subject

Name:_____Signature:_____Date:_____

Explained the consent

Name:_____Signature:_____Date:_____

Principal investigator

Name:_____Signature:_____Date:_____