Fast-track Surgery After Gynecological Oncology Surgery

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Open single center for fast-track surgery after gynaecological oncological surgery

Randomised controlled trial

Informed consent form of the patients.

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Respected patient:

You will be invited to a fast-track surgery after gynaecological oncological surgery clinical trial. Read the following carefully before you decide whether you agree to participate in the study. It can help you understand the study and why it is possible to carry out the study and the duration and duration of the study and may be given you after the study. The benefits, risks and discomfort brought about. If you like, you can also discuss with your relatives or friends, or ask your doctor to give you an explanation to help you make your decision.

1. Research background and purpose

FTS was launched in 1995 by Bardram et al. FTS is a way to promote postoperative recovery through multiple means, reduce complications, shorten hospital stay without increasing re hospitalization rate. This method has been accepted by most surgeons in the world and has been successfully used in the field of gynecologic surgery, especially in colorectal surgery. But there is no experimental report in gynecologic oncology. Present-day preoperative preparation usually includes mechanical or antibiotic bowel preparation a day before the operation, 12 hours prior to a fasting and a prohibition, excessive blood pressure rehydration, a long abdominal drainage tube and a gastric tube. They do not start eating liquid diet until after exhausting, and usually return to normal diet after 5 to 7 days. 5-7 days after the operation, the hospital was discharged. The use of FTS can accelerate recovery, reduce complications and reduce postoperative hospital stay.

2. Research process and arrangement

After signing the informed consent voluntarily to participate in the study, the doctor needs to

carry out laboratory tests for you: preoperative examination. After preliminary screening, the doctor will ask your medical history, basic situation, life signs, urine routine, liver function, kidney function and electrocardiogram. You should tell the doctor whether you have the history of allergy, past medical history, treatment and medication.

Inclusion criteria

1. Patients scheduled for gynaecological oncology surgery (including radical hysterectomy and lymphadenectomy, hysterectomy and lymphadenectomy, and cytoreductive procedures for both open and laparoscopic surgery);
2. Age: ≥ 18 years;
3. Signed informed consent provided.

Exclusion criteria

1. Patients with a documented infection at the time of surgery;
2. Age ≥ 71 years;(we discussed in ethics committee it will)
3. Patients with ileus at the time of surgery;
4. Patients with hypocoagulability;
5. Patients with psychological disorders, alcohol dependence, or drug abuse history;
6. Patients with primary nephrotic or hepatic disease；
7. Patients with severe hypertension defined as systolic blood pressure ≥ 160 mmHg and diastolic blood pressure > 90 mmHg.

If you conform to the above conditions and you will pass the preliminary screening, you will be managed according to the researcher's plan. As this experiment is a randomized controlled trial, you will be randomly divided into a rapid recovery surgery group or a traditional operation group.

In order to avoid bias, gynecologic oncology surgery has high technical requirements. All the patients in this study have doctors and nurses from the same team. The surgeon is a veteran physician.

We will keep a careful record of your preoperative, intraoperative and postoperative conditions until 21 days after discharge. When deciding whether to participate in this study, please consider carefully the possible impact of inspection and follow-up on your daily work and family life. If you have any doubt about the inspection and steps involved in the test, you can consult with us.

Please do not use other drugs at the same time without knowing the doctor's permission. During the period of observation, you have other diseases and must take drugs or other treatments. You need to report your responsible physician. He will record the drug name, usage and dosage, and take time.

During the entire study period, if there is any unusual event and related information, inform your research physician by effective way (face to face or telephone). The doctor will make a judgement and medical treatment. If the doctor finds that the treatment measures taken in this study are invalid, the study will be suspended and other effective treatments may be replaced. No matter how effective the treatment is, you need to have a relevant examination when you decide to finish your clinical research.

3. Beneficiaries' benefits, risks and compensation

During the study period, the heating equipment and oral nutrient solution needed were provided free of charge. In the process of research, any new information of this study will be announced to you in time. You will receive good medical care during the study period. According to the literature, FTS is a method to promote postoperative recovery, reduce complications, shorten hospitalization time without increasing the rate of rehospitalization. This method has been accepted by most surgeons in the world and has been successfully used in the field of gynecologic surgery, especially in colorectal surgery. The use of FTS can accelerate recovery, reduce complications and reduce postoperative hospital stay. There is no obvious adverse reaction, but different people, living habits, eating habits, and so on, can affect the effect of treatment. If you have any discomfort in the study, or any new changes in

the condition, or any accident, whether or not with the test operation, you should notify your doctor in time. The student will make a judgement and medical treatment. If the doctor finds that the treatment measures taken in this study are invalid, the study will be suspended and other effective treatments may be replaced.

If there is a adverse reaction in the clinical study, you will be given the full treatment of the doctor. If the study is directly harmful to your health, the doctor and the hospital where you participate in the study will provide the corresponding treatment in time, and the doctor or expert group determines that the study is related to the study. The applicant will provide the cost of treatment for adverse reactions related to research and diagnosis and treatment, and provide corresponding compensation in accordance with the provisions of the state regulations.

4. The right of the patient to withdraw from the study

Your participation in this study is entirely voluntary. You may choose not to participate in this study, which will not bring any adverse effects on your regular treatment. Research doctors will choose the right treatment plan for your situation. In addition, you have the right to withdraw from the study at any stage of the study. If you decide not to withdraw from this study at any time after the study and research, please contact your doctor and withdraw from the study without any penalty or loss of interest, which will not affect your relationship with the doctor, and the doctor will be based on your condition and the doctor. The principle of patient first is a reasonable treatment for you.

In case of the following circumstances, your doctor may terminate this study without your consent.

(1) Serious adverse events

(2) There were serious combined diseases during the test

(3) In violation of the research plan, it failed to follow the relevant provisions of the study, did not operate according to the doctor's guidance, or did not conduct any inspections on time.

5. The principle of confidentiality to the patients

All the information about you, including your identity, medical history, illness, physical

examination and laboratory examination results, will be strictly confidential within the scope of the law. The investigators, the inspectors appointed by the applicant, the ethics committee, and the national food and drug administration are allowed to consult your medical records related to this study to verify the authenticity and accuracy of the data collected in this study, but not to your personal details. Your name will not appear in any public information or report related to this research.

6. Research consulting

You can always consult your doctor about any problems in this study. Your research doctor's name and phone call see the informed consent signature page. In addition, if the experimental plan obtains new progress, conclusions or important events at home and abroad, the applicant will inform you in time. If you have any complaints about this research, you can contact the ethics committee of the hospital at any time.

Informed consent. Consent to the signature page

The patients stated that:

I have read and understand the informed consent of the open single center randomized controlled trial for the use of rapid rehabilitation surgery in gynecologic malignancies, and have fully understood the purpose, content, methods, and possible benefits and risks involved in the study. The doctor has explained the relevant medical terms clearly, and all the questions I have asked have been solved easily and clearly. I understand that I can refuse to join the research or suspend and withdraw research at any time and in any circumstances, and medical treatment and rights will not be affected.

I have participated in this study voluntarily and have sufficient time to take full consideration. I have learned the therapeutic effect and possible risk of the study on my disease. I have obtained the complete and true information related to this study. I fully understand and support the clinical study. In the absence of any pressure and free choice, I volunteered to participate in this clinical study, and I volunteered to cooperate with a physician to receive a physical examination to complete this clinical study.

I agree that my clinical records should be reviewed by clinical research inspectors and monitors when necessary.

I will get a copy of the signed and dated informed consent.

Patient signature: contact (telephone):

Signature of the legal representative of the patient: contact (telephone):

Date of signature:

The researchers declared:

The subject, steps, possible benefits and risks were explained in detail in the open single center randomized controlled trial for the use of rapid rehabilitation surgery after gynecologic malignancies. He gave sufficient answers to any questions raised by the patient, and the patient was satisfied with the reply and expressed his understanding. I will closely monitor and record adverse events in clinical research and take appropriate treatment measures. Make sure that the patient can get in touch with me at any time.

Doctor's signature: contact (telephone):

Date of signature: