Informed Consent

Study title: A multicenter, randomized, single-blind, parallel controlled trial to compare the efficacy and safety of three surgical approaches for laparoscopic total hysterectomy (TSALTH)

Participant: Identity Card Number:

Address:

Your current diagnose is ; We sincerely invite you to participant in this multicenter, randomized, single-blind, parallel controlled trial to compare the efficacy and safety of three surgical approaches for laparoscopic total hysterectomy (TSALTH) .The principal investigator of this study was Chief Physician Zheng Ying. This clinical trial is undertaken by the Department of Obstetrics and Gynecology of the West China Second Hospital of Sichuan University, granted by Science and Technology Department of Sichuan Province, and is approved by the Medical Ethics Committee of the West China Second Hospital of Sichuan University. This notice provides you with information to help you decide whether to participate in this clinical trial. Please read it carefully, and if you have any questions, please ask the person in charge of the clinical treatment research and the clinical doctor in charge.

1. Why we invite you to this clinical trial?

Background: Hysterectomy is the most common gynecological surgery. For the choice of surgical approach, laparoscopy is a mature gynecological technique, which has the advantages of less trauma, faster recovery, shorter hospital stays, less pain, less cost, and less scarring. In the past 5-6 years, single-port laparoscopic technology has risen rapidly. Literature reports at have confirmed that trans-umbilical laparoendoscopic single site surgery (TU-LESS) for total hysterectomy is safe and effective. The trans-vaginal natural orifice transluminal endoscopic surgery (vNOTES), emerged in recent years, is a combination of laparoscopic and transvaginal surgery. The effectiveness and safety of vNOTES hysterectomy have been reported in the literature at home and abroad. At present, the three laparoscopic surgical approaches are widely carried out in China, and they are all relatively mature technologies, but there is no parallel randomized controlled study on them.

Research purpose: This study will compare the safety and effectiveness of three different approaches of total hysterectomy through traditional multi-hole laparoscopy, TU-LESS and vNOTES.

2. What do you need to do if you take part in this research?

After screening you to be included in this clinical study, the professional clinical supervisor will fully inform you of the specific process and related risks of this clinical study. After you fully understand and voluntarily join this clinical research and sign the

informed consent, we will randomly assign you to each treatment group according to the way of drawing envelopes. A total of 480 patients were included in this study design.

During the treatment period, you are required to provide relevant information completely and truthfully, strictly follow the doctor's advice to improve relevant inspections and medications, give timely feedback on your health status and conduct regular outpatient follow-up visits.

3. What are other treatment options available?

Laparotomy for hysterectomy is the oldest surgical approach. All minimally invasive approaches can be completed through laparotomy, and there is also the possibility of conversion to laparotomy. You can also choose laparotomy. directly.

4、What are the responsibilities and obligations?

1) You need to provide complete and truthful information about your medical history and current physical condition.

2) Tell the clinician truthfully about your health problems, other medicines you take and other treatment options you have received during treatment.

3) Actively cooperate with clinicians, strictly follow the doctor's advice for medication, regular follow-up, and improve relevant inspections, with good compliance.

4) If you need to take additional medications during the treatment, you need to consult your doctor in charge.

5) You cannot participate in other medical research while in the period of clinical observation and treatment of this trial.

6) IF you have anything unclear, you can consult the clinical subject group leader or member.

5. Who will be invited to participate in this clinical study?

Eligibility Criteria

Women with the diagnosis of benign uterine disease or precancerous lesions, will be proposed to undergo total hysterectomy with or without salpingectomy/adnexectomy.

Inclusion Criteria

Patients eligible for the trial must meet all the followings.

1)Eligible women aged 18–70 years.

2)Indications for total hysterectomy (hysteromyoma, adenomyosis, cervical intraepithelial neoplasia, endometrial atypical hyperplasia, cervical adenocarcinoma in situ), planning for total hysterectomy.

3)Patients in the study approve the three surgical approaches and are willing to be randomly assigned to any of them.

4)Patients are willing to sign the informed consent.

5)Performance status of 0 or one on the ECOG (Eastern Cooperative Oncology Group) scale.

GRADE	ECOG PERFORMANCE STATUS
0	Fully active, able to carry on all pre-disease performance without restriction

1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
3	Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
4	Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
5	Dead

Exclusion Criteria

patients will be excluded for any of following reason.

1)Virginity.

2)Requiring simultaneous surgical intervention for concomitant cysts of ovaries or lesions of vulva, vagina, appendix, and so on.

3)Malignancy or highly suspected malignancy and may change the planning surgical method.

4)Twice or more pelvic surgical histories or considering severe pelvic adhesions (Rectal-Vaginal-examination suspected rectovaginal endometriosis, or poor uterine mobility).

5)History of peritoneal dialysis, pelvic radiation therapy, and previous pelvic laparoscopic tuberculosis.

6)The size of uterus is over 3 months of pregnancy (ultrasound indicates that the maximum uterine diameter line is greater than 12cm).

7)Diabetes mellitus with poor blood glucose control.

8)BMI > 30Kg/m2.

9)Patients with poor compliance or living far away for adequate follow-up.

6.How is your safety guaranteed?

This clinical trial will be carried out in West China Second Hospital of Sichuan University. The stuff of this trial have received relevant training and have sufficient ability to undertake this study. For the clinical monitoring of this research, we will dynamically monitor and evaluate the changes of your condition and decide the next treatment plan according to the situation.

7. Possible related risks and impacts?

1) Laparoscopic total hysterectomy can be accomplished by three surgical approaches, all of which are visualized laparoscopic surgery. There are complications in surgery, such as infection, bleeding, thrombus, poor incision healing, intestinal tube and ureter injury and so on. The current research of the three surgical approaches believes that the complications should be equivalent.

2) The TU-LESS and vNOTES approaches both can convert to traditional laparoscopy and all the three approaches can convert to laparotomy.

3) If malignant lesions are accidentally discovered during the operation, including but not limited to malignant transformation of uterine fibroids, endometrial atypical hyperplasia confirmed as endometrial cancer or cervical precancerous lesions in the intraoperative frozen pathology report as malignant tumors, interoperative changes or additional surgical methods are required , or the postoperative pathological examination confirmed that it was a malignant tumor and needed to be re-operated and withdraw from this study.

4) When you decide to participate in this clinical treatment research, please carefully consider the possible impact of long-term follow-up on your daily work, family life, and economic situation. The regular follow-up visits are required to ensure your safety.

5) For other unexpected related risks, we will provide you with clinical guidance when necessary.

8. What's your benefit?

During the clinical treatment research period, your condition may be improved; you can report the discomfort and adverse reactions during the research period to the relevant clinicians of this research group timely and obtain reliable clinical guidance; Related problems such as difficulty in registration and difficulty in seeing a doctor will be reduced.

Meanwhile, participating in this clinical treatment study can evaluate the safety and effectiveness of the three surgical approaches in total laparoscopic hysterectomy. This result will help you and other similar patients.

The examination and treatment expenses related to this treatment study will be borne by you personally (reimbursement by medical insurance is still applicable during hospitalization). Since each surgical approach is widely carried out clinically, this study will not increase your additional expenses.

9.Is personal information confidential?

Your research data will be kept in West China Hospital of Sichuan University, and researchers, research authorities, and ethics review committees can check your medical records. Any public reporting of the results of this research will not reveal your personal identity. We will make every effort to protect the privacy of your personal medical data and personal information within the law.

10.Do I have to take part in this trial?

Participation in this study is completely voluntary. You can refuse to participate in the study or withdraw from the study at any time at any stage of the trial without discrimination and retaliation, and your medical treatment and rights will not be affected. If you decide to withdraw from this study, please contact your doctor so that the disease can be properly diagnosed and treated.

Participant Declaration: I have read the above introduction about this study. My researchers have fully explained the purpose of this study, the operation process, the

possible risks and potential benefits of participating in this study and answered all my relevant questions. I voluntarily participate in this study.

I agree□ or refuse□ to the use of my research materials and biological specimens for research other than this one.

Print name of participant: _____

Signature of participant: _____

Date: _ _ _ _Year _ _ Month _ _ Day

Telephone number of participant: _____

Mobile number of participant: _____

_

Print name of legal representative: _____ (if applicable)

Relationship with participant: _____

Signature of legal representative: _____

Date: _ _ _ _ Year _ _ Month _ _ Day

Reason for signature of legal representative: _____

Print name of witness: _____ (if applicable)

Signature of witness : _____

Date: _ _ _ _ Year _ _ Month _ _ Day

Reason for signature of witness: _____

Doctor's statement: I have explained the relevant details of the study to the above-mentioned volunteer participating in this study and provided him/her with an original signed informed consent form. I confirm that I have explained the situation of this study to the subject in detail, especially the ethical principles and requirements such as risks and benefits, free and compensation, damage and compensation, voluntariness and confidentiality that may arise from participating in this study.

Signature of doctor: _____

Date: _ _ _ _ Year _ _ Month _ _ Day

Doctor's phone number: _____

The Medical Ethics Committee of West China Second University Hospital
Phone number: 028-85422654, 028-85423237