Clinical Study Documents■Laparoscopic Myomectomy Assisted by a Fully Enclosed Protective Device
Official Title: Laparoscopic Myomectomy Assisted by a Fully Enclosed Protective Device to Achie
ve Tumor-Free Protection Throughout the Surgical Procedure
NCT Number: NCTXXXXXXXX (to be updated after registration)
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Institution: China-Japan Friendship Hospital

Study Protocol
Background
Uterine fibroids are the most common benign tumors in women of reproductive age. Laparoscopic m
yomectomy is widely performed because of its minimally invasive advantages such as reduced bloo
d loss, faster recovery, and improved cosmetic outcomes. However, conventional morcellation tec
hniques may result in tissue dissemination within the abdominal cavity. To address this issue,
a fully enclosed protective device system was developed to maintain complete isolation of fibro
id tissue during laparoscopic myomectomy.
Study Objective
Primary Objective:
To evaluate whether the fully enclosed protective device system can achieve complete containmen
t of fibroid tissue during laparoscopic myomectomy and morcellation.
Secondary Objectives:
• Evaluate operative time
• Evaluate intraoperative blood loss
• Evaluate postoperative hospital stay
• Evaluate postoperative complications
• Evaluate histopathological outcomes
Study Design
Study Type: Observational Study
Design: Retrospective Case Series
Study Center: Single-center
Enrollment: 20 participants
Study Period: April 2025 – March 2026
Study Population
Female patients aged 28–46 years diagnosed with uterine fibroids who underwent laparoscopic myo
mectomy assisted by a fully enclosed protective device system. Fibroid diameter ranged from 6–1
0 cm.
Eligibility Criteria
Inclusion Criteria:
• Female patients aged 28–46 years
• Diagnosis of uterine fibroids confirmed by ultrasound and MRI
• Fibroid diameter between 6 and 10 cm
• Planned laparoscopic myomectomy
• Preoperative evaluation indicating benign uterine fibroids
• Provided informed consent
Exclusion Criteria:
• Suspicion of uterine malignancy
• Severe systemic disease contraindicating surgery
• Pregnancy
• Inability or unwillingness to provide informed consent
Surgical Procedure
The surgical procedure includes the following steps:
1. Establishment of pneumoperitoneum under general anesthesia
2. Introduction of the protective bag into the pelvic cavity
3. Dissection of fibroid while supported by the protective bag

4. Complete containment of fibroid tissue inside the bag
5. Establishment of an independent pneumoperitoneum inside the bag
6. Morcellation performed entirely within the sealed bag
7. Removal of fibroid tissue and protective bag together

Outcome Measures

Primary Outcome:

Integrity of the protective bag and absence of tissue leakage during laparoscopic myomectomy an d morcellation.

Secondary Outcomes:

• Operative time
• Intraoperative blood loss
• Fibroid size
• Postoperative hospital stay
• Postoperative complications
• Histopathological diagnosis

Statistical Analysis Plan

Sample Size

A total of 20 patients were included in this retrospective analysis.

Statistical Methods

Descriptive statistical analysis was used. Continuous variables are presented as mean ± standar d deviation (SD). Categorical variables are summarized as counts and percentages.

Primary Outcome Analysis

The success of the protective device system is defined as an intact protective bag with no tiss ue or fluid leakage during surgery. The success rate is calculated as the proportion of success ful procedures among all cases.

Secondary Outcome Analysis

Secondary outcomes including operative time, blood loss, and postoperative hospital stay are su mmarized using descriptive statistics.

Informed Consent Form (Template)

You are invited to participate in a clinical study evaluating a surgical technique that uses a fully enclosed protective device during laparoscopic myomectomy to prevent tissue dissemination .

Purpose of the Study

The purpose of this study is to evaluate the safety and effectiveness of a surgical technique d esigned to prevent the spread of fibroid tissue during laparoscopic myomectomy.

Procedure

If you agree to participate, you will undergo laparoscopic myomectomy using a protective isolat ion device that allows fibroid removal and morcellation within a sealed environment.

Potential Benefits

This technique may reduce the risk of tissue dissemination and improve surgical safety.

Risks

The risks are similar to those associated with standard laparoscopic surgery and may include bl eeding, infection, and injury to surrounding organs.

Confidentiality

All personal information will remain confidential and will only be used for research purposes.

Voluntary Participation

Participation is voluntary, and you may withdraw from the study at any time without affecting y our medical care.