ISRCTN41717941 https://doi.org/10.1186/ISRCTN41717941

Assessing whether using a protective bag during minimally invasive surgery to remove ovarian tumours can prevent tumour spreading during surgery

Submission date
24/01/2019

Recruitment status
No longer recruiting

Registration date
28/03/2019

Overall study status
Completed

Last Edited
28/03/2019

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Although laparoscopic surgery is widely used in many diseases, its application in ovarian tumor enucleation is still controversial. During tumor enucleation, the ovarian cortex needs to be opened; the space between the cortex and the tumor needs to be separated; the tumor needs to be removed completely and the specimen needs to be taken out through Trocar. Ovarian tumors are mostly cystic, can easily cause tumor rupture and pelvic contamination during laparoscopic surgery. If ovarian tumors are borderline tumors or malignant tumors, the damage of ovarian tumors will increase the possibility of tumor dissemination in pelvic and abdominal cavities, make malignant tumors stage upgrade or iatrogenic metastasis, and worsen the prognosis of patients. Moreover, if the tumor specimen is removed from Trocar, it may contaminate the abdominal incision and cause dissemination and metastasis of the tumor. At least 10 mm incision is needed to remove the specimen through the abdominal wall, and the incidence of incisional hernia increases after operation. Therefore, the optimization of laparoscopic enucleation and removal path of ovarian tumors is an urgent problem to be solved.

Since 2016, our team has tried to remove uterine fibroids through posterior vaginal incision, and has developed a protective bag for laparoscopic ovarian tumor enucleation (China patent application number: 201820254280.2). The use of protective bag and the removal of specimens through the posterior vaginal wall incision effectively reduce the dissemination of pelvic and abdominal contamination caused by tumor rupture. Nevertheless, at present, the number of surgical samples is small; the follow-up time is short; and the long-term impacts on vaginal microecology, vaginal scar, female sexual function and delivery are still uncertain. Thus, we aims to conduct a large-sample prospective multi-center self-control trial in 60 patients with ovarian tumors who will undergo laparoscopic ovarian tumor enucleation with the protective bag and to observe whether the protective bag can prevent the dissemination of ovarian tumors in pelvic and abdominal cavities and reduce the recurrence of ovarian tumors.

Who can participate?
Patients hospitalized for ovarian tumors requiring laparoscopic surgery.

What does the study involve?
All the patients included in the study will undergo laparoscopic surgery to remove ovarian tumors, so ovarian tumors will be wrapped with the protective bag, and the tumors will be resected in the bag to prevent tumor rupture and contamination of the pelvic cavity during laparoscopic surgery. Patients will be followed up at 2, 6 and 12 months after operation to record whether ovarian tumors recur or not, and to record vaginal length, vaginal microecology and the Female Sexual Function Index. The indications for cesarean section will be recorded if the patient undergoes cesarean section within 12 months after operation. The integrity of the posterior vaginal wall will be recorded if the patient has spontaneous delivery within 12 months after operation. The follow-up period will be 12 months.

What are the possible benefits and risks of participating?
1. All participants will receive free surgery-related examinations and postoperative evaluation, and a certain amount of transportation allowance.
2. The use of the protective bag during laparoscopic ovarian tumor enucleation will have little risk to patients.
3. To provide adequate protection, our team will provide relevant medical liability insurance. The insurance company will bear treatment costs and corresponding economic compensation for the subjects who will suffer from the damage or death related to the trial.

Where is the study run from?
Shenyang Women's and Children's Hospital, Beijing Obstetrics and Gynecology Hospital of Capital Medical University, The Second Hospital of Jilin University, China

When is the study starting and how long is it expected to run for?
From June 2019 to December 2021.

Who is funding the study?
Science and Technology Department of Liaoning Province (Natural Science Foundation Guidance Project of Liaoning Province of China)

Who is the main contact?
Ju-Min Niu
niujumin@163.com

Contact information

Type(s)
Public

Contact name
Dr Jumin Niu

Contact details
No. 87, Danan Street, Shenhe District
Shenyang
China
110011

+86-13591686272
niujumin@163.com

Additional identifiers

Protocol serial number
1.0

Study information

Scientific Title
Protective bag used in laparoscopic ovarian tumor enucleation prevents intraoperative tumor dissemination in pelvic and abdominal cavities: a prospective multicenter self-controlled clinical trial

Study objectives
It is hypothesized that the use of a protective bag and tumor removal through the midsection incision of posterior vaginal wall during laparoscopic ovarian tumor enucleation reduce the dissemination of pelvic and abdominal contamination caused by tumor rupture and decrease the recurrence rate of ovarian tumors.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of Shenyang Women’s and Children’s Hospital, China, 19/06/2018, ref. 201809.

Study design
Interventional, prospective, multicentre self-controlled clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Ovarian tumor

Interventions
A total of 90 patients hospitalized for ovarian tumors who need laparoscopic surgery will be enrolled in this trial. All patients will undergo laparoscopic ovarian tumor enucleation with a protective bag.

After general anesthesia, carbon dioxide will be injected into the abdominal cavity through the puncture site on the upper edge of the navel, and the abdominal pressure will reach 8–11 mmHg. After laparoscopic exploration, retention of flushing fluid, exposure of rectouterine pouch, the peritoneum on the surface of rectal attachment will be opened, and the rectum will be pushed down. Simultaneously, the middle part of the posterior vaginal wall (4–5 cm from the

vaginal orifice) will be lifted by a self-made vaginal separator in the vagina. The connective tissue between the posterior vaginal wall and the rectal space was separated to fully expose the posterior vaginal wall. The length of the transverse incision of the posterior vaginal wall through the medial side of the left and right sacral ligaments will be determined by the tumor size. The protective bag for laparoscopic ovarian tumor enucleation will be inserted through the posterior vaginal wall incision. The tumor will be placed into the protective bag and resected in the bag to prevent tumor extravasation. The 1-0 absorbable suture will be used to suture the peritoneum in the rectouterine pouch. After rinsing the abdominal cavity, the flushing fluid will be retained for examination. The two flushing fluids will be compared to check the presence of residual tumor cells. After relieving pneumoperitoneum, the 2-0 absorbable sutures will be utilized to suture vaginal mucosa intermittently.

Intervention Type
Device

Primary outcome(s)
Recurrence rate of ovarian tumors within 12 months after surgery.

Key secondary outcome(s))
1. Number of tumor cells in peritoneal flushing fluid before and after surgery
2. Difference of vaginal length before and 2, 6, and 12 months after surgery
3. Change of vaginal microecology before and 2 months after surgery:
3.1. Vaginal secretions will be smeared, dried, fixed, and then receive Gram’s staining. Vaginal flora will be examined under the oil immersion lens, including dominant bacteria, microbial concentration, microbial diversity, trichomonas, and fungi.
4. Sexual function will be measured using the Female Sexual Function Index before and 6 and 12 months after surgery.
5. Indications for cesarean section will be recorded if the patient undergoes cesarean section within 12 months after operation.
6. Integrity of posterior vaginal wall after spontaneous delivery will be recorded if the patient has spontaneous delivery within 12 months after operation.

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Ovarian cysts persist or increase, and the diameter of cysts lasts more than 5 cm before and after menstruation.
2. Age of 18 to 50 years old.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Severe heart, lung, liver, and kidney dysfunction.
2. The space is limited for the operation in the pelvic and abdominal cavities, and the mass obstructs the field of vision; pneumoperitoneum or puncture may cause tumor rupture.
3. Breastfeeding and pregnant women.
4. Patients suspected of having deep invasive endometriosis before operation.
5. Participation in other clinical trials.

Date of first enrolment
01/12/2019

Date of final enrolment
01/12/2020

Locations

Countries of recruitment
China

Study participating centre
Shenyang Women's and Children's Hospital
No. 87, Danan Street, Shenhe District
Shenyang
China
110011

Study participating centre
Beijing Obstetrics and Gynecology Hospital, Capital Medical University
No. 251, Yaojiayuan Road, Chaoyang District
Beijing
China
100006

Study participating centre
The Second Hospital of Jilin University
No. 218, Ziqiang Street, Nanguan District
Changchun
China
130022

Sponsor information

Organisation
Shenyang Women’s and Children’s Hospital

Funder(s)

Funder type
Government

Funder Name
Natural Science Foundation Guidance Project of Liaoning Province of China 20180550500

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes