#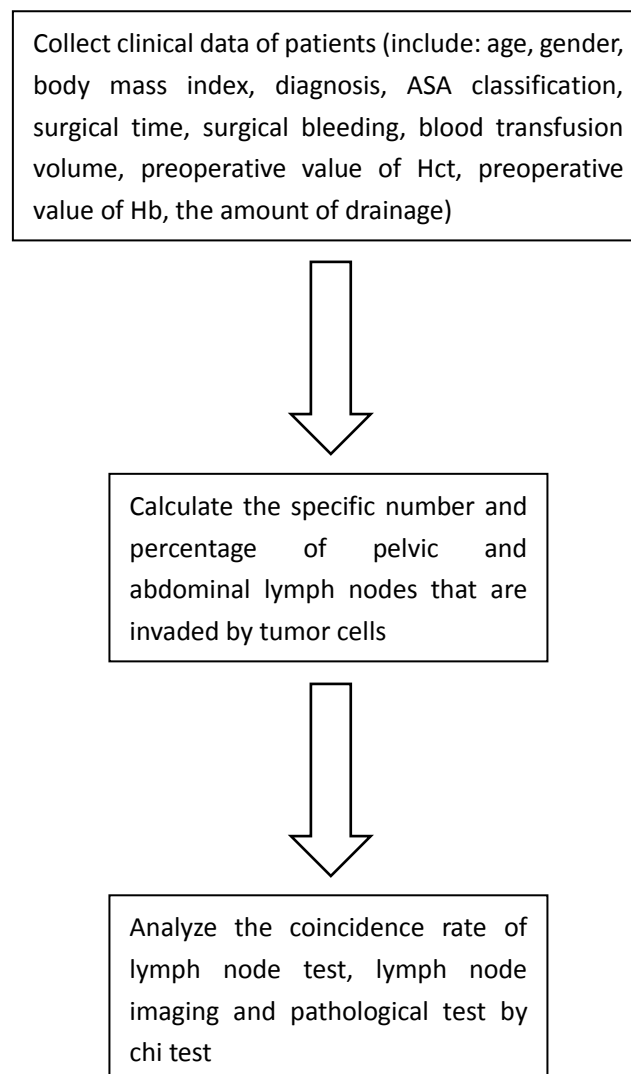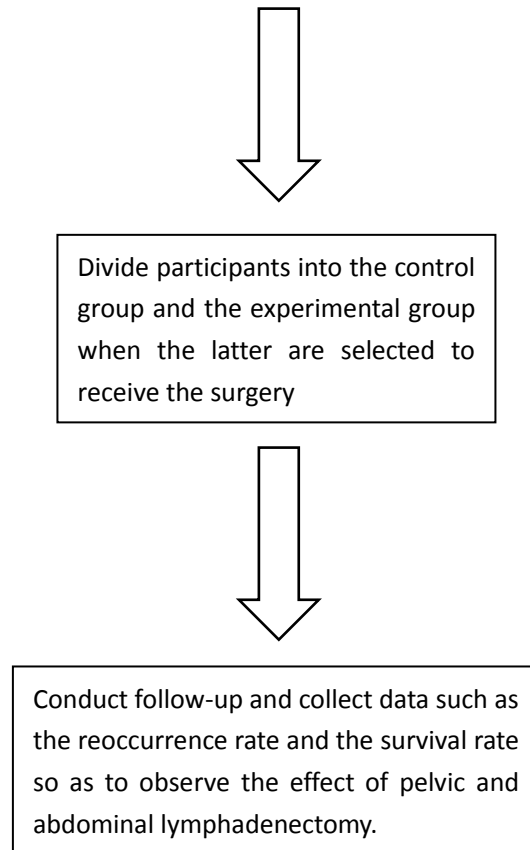 A Research on the Clinical Significance of Sentinel Lymph Node Imaging Combined With Imaging Examination in Pelvic and Peritoneal Lymphadenectomy for Endometrial Carcinoma

2019.02.01

Study objectives The primary objective of this study is to identify the specific number and percentage of pelvic and abdominal lymph nodes that are invaded by metastatic endometrial carcinoma, and to calculate the coincidence rate of lymph node imaging and pathological examination. By setting up the control group and experimental group, we plan to find out whether pelvic and abdominal lymphadenectomy would exert positive effect on patients with endometrial carcinoma.

Trial design This is a prospective interventional trial. After signing of informed consent, the electronic medical data of patients with endometrial carcinoma will be collected in this study. The specific number and percentage of pelvic and abdominal nodes that are invaded by tumor cells well be calculated. By combining the imaging results and pathological test, we plan to obtain the coincidence rate of three tests. Finally, we would randomize patients into the control group and the experimental group as to receive the pelvic and peritoneal lymphadenectomy. When their postoperative data such as the reoccurrence rate and the five year survival rate are compared, the effect of pelvic and peritoneal lymphadenectomy on the prognosis of endometrial carcinoma are drawn.

Collect clinical data of patients (include: age, gender, body mass index, diagnosis, ASA classification, surgical time, surgical bleeding, blood transfusion volume, preoperative value of Hct, preoperative value of Hb, the amount of drainage)

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Calculate the specific number and percentage of pelvic and abdominal lymph nodes that are invaded by tumor cells

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Analyze the coincidence rate of lymph node test, lymph node imaging and pathological test by chi test

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┌─────────────────────────────┐
│ Divide participants into the control │
│ group and the experimental group    │
│ when the latter are selected to      │
│ receive the surgery                  │
└─────────────────────────────┘
        ↓
┌─────────────────────────────┐
│ Conduct follow-up and collect data such as │
│ the reoccurrence rate and the survival rate │
│ so as to observe the effect of pelvic and   │
│ abdominal lymphadenectomy.                  │
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Sample size The planned sample size was based on data from a previous study, in which the standard deviation was 5. We assumed an one-tailed α error of 0.05 and a sampling error of 1.0. We propose to enroll 70 participants including 35 patients in the control group and the others in the experimental group, and allow for a dropout rate of 10% for an effective sample size of 60.

Inclusion criteria

1. Volunteer to participate in the study with informed consent;

2. Females aged 10-90 who are confirmed with endometrial carcinoma and are willing to receive primary non-reserved fertility function surgery.

Exclusion criteria

1. Pregnancy, lactation, postmenopause, or planned pregnancy within two years;

2. Suspected or identified as other tumors of genital tract;

3. History of hyperparathyroidism, infectious diseases (tuberculosis, AIDS), autoimmune diseases, or digestive system diseases (malabsorption, crohn disease and dysentery);

4. Other diseases or heavy injuries that will interfere with the results;

5. Simultaneous participation in another clinical study with investigational medicinal product(s) or researcher thinks the subjects are not suitable for this trial.

Withdrawal Subjects must be withdrawn from the study when one of the following criteria occurs:

1. At their own request. At any time during the study and without giving reasons, a subject may decline to participate further. The subject will not suffer any disadvantages as a result;

2. In the investigator's opinion, continuation of the study treatment would be harmful to the subject's health;

3. Obvious non-compliance;

4. Lost to follow-up;

5. Pregnancy;

6. Other medical or surgical treatments of endometrial carcinoma.

Safety assessments

Safety will be assessed by renal and liver function test, electrolyte, routine blood test. Other indicators are detected during the operation and rehabilitation period. The occurrence of any adverse events in participants will be recorded in the case report forms during each patient visit. We will withdraw patients who have severe adverse events, as it is unsafe for them to continue the trial. Meanwhile, we will give them relevant medical care and follow them up until the reaction has terminated.

Statistic analysis

The specific number and percentage of pelvic and abdominal lymph nodes that are invaded by tumor cells are collected. Multiple linear regression analysis was applied to evaluate the risk of lymphatic metastasis related to fourteen independent variables including four qualitative variables (hypertension, diabetes, diagnosis according to the FIGO staging system and the pathological tumor type) and eight quantitative variables(age, BMI, the number of lymph nodes, the interval between biopsy and operation, surgical time, surgical bleeding, postoperative anticoagulant time, preoperative value of Hb, preoperative value of RBC and preoperative value of Hct). All statistical analyses were performed by SPSS 17.0 software package and the level of statistical significance was set at $P<0.05$. All independent variables were incorporated into the model using the method of "Enter". Data are presented as mean±standard deviation. Meanwhile, we collect the lymph node imaging results and the pathological test results so as to investigate the coincidence rate of the three examinations by chi test. As to the analysis of the lymphadenectomy on patients, we would conduct corresponding statistical method to interpret the follow-up data.