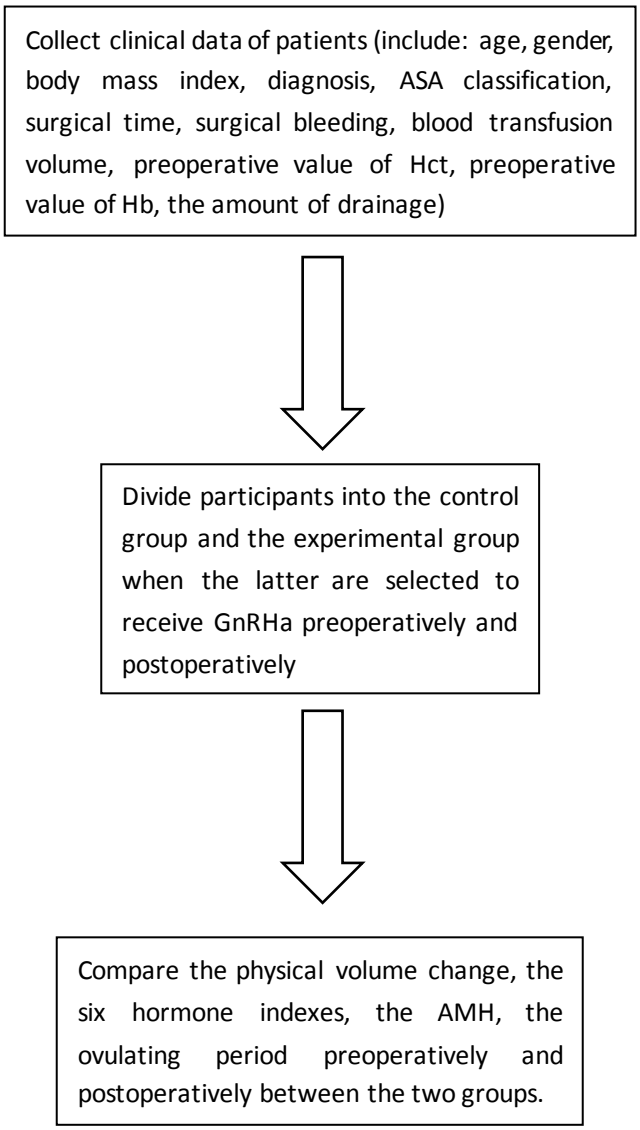
A Research on the Ovarian Function Detection and Protection in Fertility Preservation Surgery for Ovarian Malignancy

2019.02.01

Study objectives The primary objective of this study is to identify whether applying GnRHa on patients with ovarian malignancy for fertility preservation surgery preoperatively and postoperatively has a different outcome. By comparing the physical and hormone indexes in the control group and experimental group, we plan to find out the effect of GnRHa.

Trial design This is a prospective interventional trial. After signing of informed consent, the electronic medical data of patients with ovarian malignancy will be collected in this study. 20 patients will be enrolled in this trial. They well be randomized into the control group and the experimental group as to receive GnRHa for fertility preservation surgery preoperatively and postoperatively. We plan to investigate into the effect of GnRHa by monitoring the physical ovarian change and the six hormone indexes in the two different groups.



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 24 participants including 12 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 20.

Inclusion criteria

1. Volunteer to participate in the study with informed consent;
2. Females aged 10-90 who are confirmed with ovarian malignancy and are willing to receive fertility preservation surgery.

Exclusion criteria

1. Suspected or identified as other tumors of genital tract;
2. History of hyperparathyroidism, infectious diseases (tuberculosis, AIDS), autoimmune diseases, or digestive system diseases (malabsorption, crohn disease and dysentery);
3. Other diseases or heavy injuries that will interfere with the results;
4. 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Withdrawal Subjects must be withdrawn from the study when one of the following criteria occurs: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

Before the enrollment of participants, patients' medical data will be collected and analyzed to evaluate whether they are suitable for this trial. With their informed consent, they will be randomized into the control group and the experimental group. The situation of the two group will be almost the same considering the average age, the average BMI, the average grading evaluation. The fertility preservation surgery means the ovary affected by cancerous cell is resected when the other is preserved. If the other side was already resected, the ovarian tumor on the affected side will be removed. Before and after the operation, patients in the control group will receive placebos when the experimental group will receive GnRHa. The physical ovarian volume, six hormone indexes, AMH and the ovulating period will be monitored and compared by chi-square analysis in SPSS 17.0.