浙江省人民医院
ZHEJIANG PROVINCIAL PEOPLE'S HOSPITAL

Drug Clinical Trial Agency Document (Institutional Office)

Additional file 3: patient consent form in English

Clinical Research Informed Consent Form of Zhejiang Provincial People's Hospital (Version 1, September 3, 2018)

Dear patient:

You are already diagnosed as _____. We will invite you to participate in a Clinical study Effects of intraoperative PEEP on postoperative pulmonary complications in high-risk patients undergoing laparoscopic abdominal surgery. This study is a self-financing project, research number:_____. This study protocol has been reviewed by the Ethics Committee of Zhejiang Provincial People's Hospital and was agreed to conduct this clinical research.

Please carefully read the following items before you decided to participate in this study. It can help you understand the meaning and objectives of this research, the procedures and duration of this study, the benefits, risks and discomforts that you may be meat after participating in this study. You can also discuss with your kins or friends, or ask for an explanation from your doctor to help you make a decision.

I. Introduction:

Every year around the world, approximately 230 million patients require surgery with general anesthesia and mechanical ventilation. Laparoscopic surgery has been widely accepted because it is associated with less blood loss, less postoperative pain and rapid recovery. The incidence of postoperative pulmonary complications (PPCs) in patients undergoing general surgery is approximately 5%, and 12% to 58% of patients undergoing abdominal surgery will develop a PPC. Furthermore, PPCs are strongly associated with prolonged postoperative hospital stays and a higher risk of mortality.

Compared with nonprotective mechanical ventilation without PEEP, a number of studies have shown that the use of a lung-protective ventilation strategy has a lung-protective effect in patients with healthy lungs who are undergoing abdominal surgery, reducing the incidence of PPC. Despite all these studies recommend the use of low tidal volume, the appropriate PEEP has not yet been defined.. When high PEEP is applied, alveolar may be overinflate and pulmonary vascular resistance is likely to increase; however, use of low PEEP may not prevent atelectasis.

It should also be noted that all these studies included only open surgeries or various types of abdominal surgery; they did not include patients planning to undergo laparoscopic surgery. Some studies have suggested that laparoscopic-assisted gastrectomy (LAG) was beneficial for postoperative respiratory function recovery. Nevertheless, it is also necessary to consider the effects of pneumoperitoneum (PnP) on airway pressure and pulmonary function.

The role of PEEP during the intraoperative period in preventing PPCs for laparoscopic surgery has not been clearly defined. We hypothesized that, when compares to low PEEP, standard PEEP may prevent the incidence of PPCs and may reduce the occurrence of organ dysfunction. These anticipated results may further improve our knowledge regarding the effects of intraoperative PEEP on postoperative pulmonary complications, survival rates and; in-hospital stays in patients undergoing laparoscopic surgery.

Objectives of the study:

This trial aimed to compare the effects of low tidal volumes combined with standard PEEP (6-8 cmH2O) with those of low PEEP (≤ 2 cm H_2O) in patients at risk for complications undergoing laparoscopic surgery during general anesthesia in terms of: (1) PPCs, (2) modified clinical pulmonary infection score (mCPIS), postoperative extrapulmonary complications, changes in chest X-ray findings, and oxygenation; (3). intraoperative complications including hypoxemia, massive transfusion; and (4) postoperative surgical complications, intensive care unit (ICU) lengths of stay, hospital lengths of stay and thirty-day mortality.

II. The process in participating this study:

1) You should cooperate with the medical staff to complete the relevant preoperative preparation according to the clinical routine requirements.

2) You should truly provide the information of related examination and treatment, so that the researcher can accurately carry out the research-related assessment.

3) If you meet inclusion criteria, you can voluntarily choose to participate in this study and sign the informed consent form, and you may be randomly assigned to the standard PEEP group (control group) and low PEEP group (processing group).

4) We will test and record your blood routine and blood gas analysis during the research in the first, the third and he 7th postoperative day. We will take 3 ml of blood for laboratory tests each time.

III. The possible benefits of this study

1. Personal benefit: the setting of intraoperative mechanical ventilation parameters has a significant impact on postoperative pulmonary complications, hospital stay and mortality in patients undergoing abdominal surgery. Airway pressure monitoring and blood gas analysis are clinically commonly used to reflect lung function during surgery period, however, lung compliance measurement is not routinely performed. We will all do the above measurements to monitor your lung function no matter which group you are assigned to during the study. The responsible clinician will take steps according to the examination results, even he can terminate the clinical research at any time. In this study, patients experienced PPCs may be detected out early and the rate of PPCs may be reduced, and it might improve your recovery. Furthermore, 3 ml of the blood sample required for each test will not affect your health.

2. Social benefits: Current studies shows that the use of a lung-protective ventilation strategy has a lung protection effect in patients undergoing abdominal surgery, however, the role of positive endexpiratory pressure (PEEP) during the intraoperative period in preventing PPCs for laparoscopic surgery has not been clearly defined. We hypothesized that, when compares to low PEEP, standard PEEP may prevent the incidence of PPCs and may reduce the occurrence of organ dysfunction.

IV. **Risks and measures of this study:** (probable adverse reactions, coping solution, compensation measures, treatment costs, claims and etc.)

Many studies have confirmed that the use of low tidal volume combined with PEEP can reduce PPCs in patients undergoing abdominal surgery. We also routinely use PEEP to prevent lung collapse and PPCs. You have about 50% chance of being assigned to the standard PEEP group, and you may be in a risk of potentially high airway pressure. However, we will monitor the airway pressure, blood gas and lung compliance measurement analysis throughout the operation to fully analyze your lung function. The responsible clinician will take steps according to the examination

results, even he can terminate the clinical research at any time.

Prevention measures for the risk of intraoperative high airway pressure:

1 sucking; 2 increase inhalation anesthesia; 3 reduce tidal volume to 6 ml/kg (PBW); 4 gradually reduce PEEP to 0; 5 changed to pressure control mode ventilation. Any research investigator will immediately notify the moderator if there is any suspected adverse event or any ethical issues regarding the study (Liaison: Zhou zhen-feng: 13685856148; PI: Hu Shuang-fei: 13777858909).

V. Relevant expenses:

Our research group is responsible for the cost of blood gas testing, but this study does not increase the cost of other drugs as compared to the clinical routine. Patients and health insurance or third-party payers will not pay for research-related medical care. Research institutions will be responsible for research-related support (including central laboratories). Subjects and health insurance or third-party payers are required to pay for routine or non-study-related medical care. These routine medical treatments include hospitalization and other medical care at discharge.

This study did not increase the cost of drugs and increased the risk of clinical treatment as compared to clinical routine treatment. You can voluntarily choose to participate in this study without relevant economic compensation. We will afford relevant economic compensation after consultation with the patients if adverse events are happened including information leakage, infringement of life rights, certain damage and other events..

VI.Your power:

You will be completely voluntary to participation in this study. You can withdraw from the study at any time without any reason. It will not affect your relationship with the medical staff, future diagnosis and treatment. All your personal data and observation records will be kept in confidential and will be only used for this study. You can obtain any relevant information during this study. You can contact the responsible physician when there is a any problem or you just need to consult the relevant questions.

VII. The ethics committee

This study has been reported to the People's Hospital of Zhejiang Province Human Research Ethics Committee and it has been approved after comprehensive review and assessment the risk of this study. You can contact the Ethics Committee about any relevant ethics and rights issues during the study. Telephone for 08:00-17:00 is 0571-85893643 and 15671110068 for other time. Email address: zryllwyh@163.com.

Informed consent form. the agreement signature page

Agreement statement

As a patient, I have understand the purpose, methodology, possible treatment benefits and possible adverse effects of this study. I will receive a copy of the signed informed consent form with my name and signed time .

I am willing to participate in this study and ensure that I will follow the doctor's advice as much as possible.

Patient signature:_____ Date:_____

Telephone number: _____

I confirm that I have explained the details of this study to the patient including his powers, possible benefits and risks. I have afforded him a copy of the signed informed consent.

Doctor signature:_____ Date:_____

Doctor Telephone number: _____