Participant Consent Form

Project: Developing a magnetic-assisted-POCUS guided bronchoscope among patients with suspected difficult endotracheal intubation

Contact Address:

<table>
<thead>
<tr>
<th>Dr Yuan Tian</th>
<th>Dr Chunhua Yu</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anesthesiology Department, Peking Union Medical College Hospital, Dongcheng District, Beijing, China</td>
<td>Anesthesiology Department, Peking Union Medical College Hospital, Dongcheng District, Beijing, China</td>
</tr>
<tr>
<td>Email: <a href="mailto:tianyuan95@pumch.cn">tianyuan95@pumch.cn</a></td>
<td>Email: <a href="mailto:Yu.chunhua@aliyun.com">Yu.chunhua@aliyun.com</a></td>
</tr>
<tr>
<td>Contact number: 008617611356059</td>
<td>Contact number: 00861069152001</td>
</tr>
</tbody>
</table>

Date: Mar, 2022

Background information

General anesthesia tracheal intubation is the primary anesthetic method to ensure the completion of surgery and patient safety. Detection of unintended tracheal intubation is an important step in this method and is an important factor in reducing anesthetic accidents and ensuring postoperative regression. Real-time ultrasound is a rapid, non-invasive detection method that potentially benefits patients with difficult intubation.

In our study, patients willing to participate in this study and at risk for difficult intubation were randomly assigned to either the ultrasound-assisted laryngoscopic view or the laryngoscopic view group, and the location of tracheal intubation was detected using noninvasive cervical ultrasound-assisted intubation with laryngoscopic view or laryngoscopic view at the same time as tracheal intubation to assess the difference in the effectiveness of the two methods. In order to obtain data related to the application of ultrasound-assisted methods for detecting the position of intubation in patients with difficult intubation.

Our study can provide more valuable evidence for clinical decision making in the refinement of airway management in patients with difficult tracheal intubation. Your participation will make an important contribution to obtaining such evidence, allowing other patients to benefit from your contribution.

Who should not participate in the study?

There are strict inclusion and exclusion criteria for this study. Any patient who does not meet the inclusion criteria should not participate in this study, in addition to 1) patients who are participating in other clinical studies; 2) those who are considered by the investigators to be unsuitable for clinical studies for other reasons.

What will I need to do if I participate in the study?

1. Before you are enrolled in the study, your doctor will ask questions, record your
general condition, and assess whether you are at risk for difficult intubation. It will be
determined that you are an eligible inclusion, that you are volunteering for the study,
and you will be asked to sign an informed consent form.
2. If you volunteer to participate in the study, we will perform a standard or
ultrasound-assisted protocol for you, depending on the randomization group, and
record the monitoring results.

Possible benefits of participating in the study.
If you participate in the study, the results of the study will have important implications
for clinical decision making in all general anesthesia tracheal intubation populations
and will provide you with the following improved support for evaluation and consultation during your anesthesia. This includes:
1. better assessment measures: including more detailed and improved airway assessment. There are no tests outside of the current treatment routine, which will not increase the cost of your treatment, and if additional tests are incurred as a result of the study itself, they will be free of charge to you.
2. Specialized visits and consultations: The visits and consultations of this project will be conducted by specially trained personnel, so that you can receive timely and comprehensive consultations on the contents related to general anesthesia tracheal intubation, and your relevant questions will be answered and dealt with in a timely manner.

Possible risks, adverse reactions and discomfort, inconvenience of participating in the study.
This project uses laryngoscopic visualization alone and ultrasound-assisted laryngoscopic visualization; laryngoscopic visualization is a routine clinical method and ultrasound-assisted method is a non-invasive method, so participation in this project itself will not increase your risk.
You will be required to participate in airway evaluations during the study, and these will take up some of your time and may also cause you problems or inconvenience.
If you experience any discomfort after the clinical study, including during the study, or if there are any new changes in your condition, or any unforeseen circumstances, whether or not related to the study, you should promptly notify your physician, who will make a determination and provide appropriate medical treatment.

Related Costs and Compensation
There are no additional anesthetic risks or costs associated with either of the methods involved in this study, and the patient is responsible for the costs associated with routine anesthetic management. Treatments and examinations required for your concurrent medical conditions will also not be covered free of charge. However, if additional tests are performed as a result of the program itself, they will be free of charge to you.
The intervention methods involved in this study are non-invasive and routine, and will not cause damage to the patient, so there is no compensation involved in this project.
Is personal information confidential?
Your medical records (study charts/CRFs, labs, etc.) will be kept intact at the hospital you visit. Your doctor will record the results of laboratory tests and other examinations in your medical record. The investigator, ethics committee and drug regulatory authorities will be given access to your medical records. Records of all your personal information, including name, phone number, email, and address, will not appear in electronic databases, and any public reports of the results of this study will not disclose your personal identity and information. We will make every effort to protect the privacy of your personal medical information to the extent permitted by law.

How can I get more information?
You can ask any questions about this study at any time and get the appropriate answers. For inquiries (investigator contact): 17611356059; and you have the right to ask questions about your rights or related risks, inquiries (ethics review committee contact): 69156874
Your physician will promptly notify you of any important new information during the study that may affect your willingness to continue to participate in the study. You can voluntarily choose to participate in the study and withdraw from the study. Participation in the study is entirely at your discretion. You may refuse to participate in the study or withdraw from the study at any time during the study, and this will not affect the relationship between you and your physician, nor will it affect your medical treatment or any other loss of benefits.

Your physician or investigator may discontinue your participation in this study at any time during the study for reasons of your best interest.
If you withdraw from this study for any reason, you may also be asked to undergo laboratory tests and physical examinations if your doctor deems it clinically necessary.

What should I do now?
It is up to you (and your family) to decide whether to participate in this study. Please ask your doctor as many questions as possible before you make a decision to participate in the study.
Thank you for reading the above materials. If you decide to participate in this program, please tell your doctor and he/she will make all the arrangements for you to participate in the study. Please keep this information with you.

Statement of Consent
I have read the above description of this study and have had the opportunity to discuss and ask questions about this study with my doctor. All of the questions I have asked have been answered to my satisfaction.
I am aware of the possible risks and benefits of participating in this study. I understand that participation in this study is voluntary, I acknowledge that I have had sufficient time to consider it, and I understand that I can ask my doctor for more information at any time.
I may withdraw from this study at any time without discrimination or reprisal, and without my medical treatment or rights being affected in any way. I am equally aware that if I withdraw from the study in the middle of the study, especially if I withdraw for medication reasons, it would be very beneficial to the study as a whole for me to inform my physician of any changes in my condition and to complete the appropriate physical and physical examinations. If I need to take any other medication due to a change in my condition, I will consult my doctor beforehand or tell him/her truthfully afterwards. I give my consent to the drug regulatory authority, ethics committee or sponsor's representative to access my study data. I will be provided with a signed and dated copy of the informed consent form. Finally, I have decided to give my consent to participate in this study and I promise to follow medical advice as far as possible.

Subject's name

Subject's signature

Date

If the patient has appointed a legal proxy (if applicable, and signed a proxy agreement):

Name of legal attorney (in block letters)

Signature of legal attorney

Date

I confirm that the details of this study, including their rights and possible benefits and risks, have been explained to the patient and that they have been given a copy of the signed informed consent form.

Name of investigator

Signature

Date