Practice name:
Participant ID:

Informed Consent

Informed Consent form for patient.

This Informed Consent Form is for men and women who attend Shanghai Pulmonary Hospital and who we are inviting to participate in research on anesthesia for bronchoscopy.

The title of our research project is: *Sufentanil target controlled infusion (TCI) vs remifentanil TCI for monitored anaesthesia care for patients with severe tracheal stenosis undergoing fiberoptic bronchoscopy*.

Principal Investigator: Jianming Liu, MD
Organization: Department of Anaesthesiology, Shanghai Pulmonary Hospital, Tongji University School of Medicine

This Informed Consent Form has two parts:

1. Information Sheet (to share information about the research with you)
2. Certificate of Consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form

PART 1: Information Sheet

Introduction

I am Jianming Liu, working for department of Anaesthesiology. We are doing research on monitored anaesthesia care for patients with severe tracheal stenosis undergoing fiberoptic bronchoscopy. I am going to give you information and invite you to be part of this research.

You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research. There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the study doctor or the staff.)

Purpose of the research

Bronchoscopy has been an integral part of the diagnosis and treatment of patients with tracheal stenosis. The two opioids most commonly used are sufentanil and remifentanil. We aim to conduct a trial comparing sufentanil with remifentanil in patients with severe tracheal stenosis undergoing fiberoptic bronchoscopy.

Participant selection

We are inviting all adults with severe tracheal stenosis attend Shanghai Pulmonary Hospital to participate in the research.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will offer the treatment that is routinely offered, and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier.

Procedures and Protocol

Participants will be randomly assigned to one of two groups. Participants in one group will be given monitored anesthesia care (MAC) using sufentanil target controlled infusion. Participants in the other group will be given monitored anesthesia care (MAC) using remifentanil. We will then compare which of the two has the best results. The healthcare workers will be looking after you and the other participants very carefully during the study. If we are concerned about what the treatment is doing, we will find out which treatment you

are getting and make changes. If there is anything you are concerned about or that is bothering you about the research please talk to me or one of the other researchers.

For any clinical study (if relevant):

We will take arterial blood from your arm using a syringe through arterial line. This blood taken is painless. In total, we will take about 2 samples of 1 ml arterial blood. At

the end of the research any left-over blood sample will be destroyed).

Description of the Process
In the first time, a small amount of blood, equal to about a teaspoon, will be taken from your arm with a syringe through arterial catheter. This blood will be tested with a blood analyzer. We will ask you a few questions about your general health.
You'll be anesthetized during fiberoptic bronchoscopy. After treatment we'll draw your blood and also ask you a few questions.

Duration
The research takes place over 1/2 days.

Risks
Any risk can appear during the process. Mechanical complications of fiberoptic bronchoscopy include nasopharyngeal, vocal cord, and airway trauma as well as bronchospasm, laryngospasm, pulmonary derecruitment/atelectasis, pneumothorax, airway hemorrhage, and introduction or exacerbation of infection. Systemic complications are primarily related to the procedure itself, medication administration, or patient comorbidities. The healthcare workers will be looking after you and the other participants very carefully during the study. If we are concerned about what the treatment is doing, we will find out which treatment you are getting and make changes.

Benefits
If you participate in this research, you will have the following benefits: any interim illnesses will be treated at no charge to you. The Fresenius DPS workstation for TCI used for free. Your participation is likely to help us find the answer to the research question.

Reimbursements
Your participation is free. You will not be given any other money or gifts to take part in this research.

Confidentiality
With this research, something out of the ordinary is being done in your community. It is possible that if others in the community are aware that you are participating, they may ask you questions. We will not be sharing the identity of those participating in the research.
The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [Yi Zhou and Jianming Liu) who will have access to the information.

Sharing the Results

The knowledge that we get from doing this research will be shared with you through community meetings before it is made widely available to the public. Confidential information will not be shared. After these meetings, we will publish the results in order that other interested people may learn from our research.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.

Alternatives to Participating

If you do not wish to take part in the research, you will be provided with the established standard treatment available at our hospital.

Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:
DR. Jianming Liu, Phone: 86-18019285297
This proposal has been reviewed and approved by the Ethics Committee of Shanghai Pulmonary Hospital of China (approval No. K19-122) which is a committee whose task it is to make sure that research participants are protected from harm.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART 2: Certificate of Consent

This section should be written in the first person and have a statement similar to the one in bold below. If the participant is illiterate but gives oral consent, a witness or a legally authorized representative must sign. A researcher or the person going over the informed consent must sign each consent. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

		Please initial each box
1	I have read the foregoing information, or it has been read to me.	☐
2	I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction.	☐
3	I consent voluntarily to participate as a participant in this research.	☐

Print Name of Participant _____

Signature of Participant _____

Date(Day/month/year) _____

If illiterate

Aliterate witness or legally authorized representative must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

		Please initial each box
1	I have witnessed the accurate reading of the consent form to the potential participant	☐
2	I have witnessed the individual has had the opportunity to ask questions.	☐
3	I confirm that the individual has given consent freely.	☐

Print Name of witness or legally authorized representative _____

Signature of witness or legally authorized representative _____

Date(Day/month/year) _____

Thumb print of participant ☐

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher _____

Signature of Researcher _____

Date(Day/month/year) _____