EFFECT OF PLACING THE ENDOTRACHEAL TUBE BEYOND CERVICAL C7 LEVEL IN ANTERIOR CERVICAL DECOMPRESSION AND FUSION SURGERY: AN OBSERVATIONAL STUDY ON ENDOTRACHEAL CUFF PRESSURE CHANGES

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PARTICIPANT INFORMATION SHEET

Research Title:
Effect Of Placing The Endotracheal Tube Beyond Cervical C7 Level In Anterior Cervical Decompression And Fusion Surgery: An Observational Study On Endotracheal Cuff Pressure Changes

Introduction:
You are invited to participate in a research study. Before participating in this study, it is important that you take time to read and understand the information in this Information Sheet.

Purpose of Study:
You will be undergoing neck surgery called anterior cervical decompression and fusion (ACDF) surgery for your neck issue. This will involve skin incision to expose your neck bone, then surgeon will remove part of the diseased bone and fix it with metal screws and plate. The surgeon will be operating from the front of your neck. During anaesthesia, you will be made unconscious using intravenous drugs and a medical tube will be placed through your throat into your windpipe (trachea) for delivery of oxygen. This tube has a cuff that seal around your windpipe for it to function properly. During the surgery, the surgeon will be using a tool called retractor to reach the site of operation. There are many studies that showed that during retraction, the cuff of the medical tube was compressed directly and cause tremendous pressure to windpipe and caused many complications such as sore throat, difficulty in swallowing and hoarseness of voice after operation. We plan to address this issue by placing the medical tube deeper into your windpipe so that the cuff will be beyond the surgery site. By doing so, there will be less likely chance of the surgery retractor compressing on the cuff of the medical tube directly.

What will the study involve?
Your anaesthesia and surgery procedures will be of no difference to any other patients undergoing similar surgery. We will be placing the medical tube deeper into your windpipe when you are unconscious. The placement of this medical tube will then be check again by listening to your breath sound, and then reconfirmed by using a flexible camera through the medical tube to make sure the tube is delivering oxygen to both your lungs adequately. Lastly, we will also be checking the tube through a Xray machine while your surgeon is using the machine to ascertain the site of the operation.

During the surgery, we will be observing and record the seal pressure continuously to keep in within normal range. After he operation, we will ask you regarding a few symptoms such as sore throat, difficulty in swallowing and voice changes.

Benefits:
By participating in this study, you will have the direct benefit of the cuff pressure being monitored in real time. This study may or may not help to reduce the symptoms such as sore throat, difficulty in swallowing and voice changes after your surgery. However, your participation could help us improve on the prevention of extreme changes to cuff pressure in future patients.

Risks

The usual surgical and anaesthesia risk associated with this ACDF surgery is similar to other patients. However, there is a small risk of the medical tube being placed too deep and result in the delivery of oxygen to one side of your lung only. We will prevent this from happening by performing the three procedures (listening to lungs, viewing directly with a flexible camera and using the Xray machine) as mentioned earlier.

Do you have to take part?
Participation in this study is voluntary. If you agree to take part, then you will be asked to sign the "Informed Consent Form". You will be given a copy of the form and this Information Sheet.

Your treatment is not affected if you decide not to participant in this study. You will undergo surgery under general anaesthesia as usual and your anaesthetist may or may not monitor the tracheal tube cuff pressure during surgery.

Should you decide to participate, you can still withdraw from the study without penalty. Your data will not be used and will be discarded. The researcher may also remove you from the study for a variety of reasons. In this event, you will not be penalised or lose your rights as a patient.

Data & Confidentiality:
The data from this study will be made into a report which may be published. Access to the data is only by the research team of UKM. The data will be reported in a collective manner with no reference to an individual. Hence your identity will be kept confidential.

Payment and compensation:
You do not have to pay nor will you be paid to participate in this study. You will have to have to pay for the usual hospital charges.

Who can I ask about the study?
If you have any questions, you can direct them to the research team. You can also contact the REC UKM for clarifications.

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PARTICIPANT INFORMED CONSENT FORM

Research Title:
Effect Of Placing The Endotracheal Tube Beyond Cervical C7 Level In Anterior Cervical Decompression And Fusion Surgery: An Observational Study On Endotracheal Cuff Pressure Changes

Researcher's Name: Dr Liu Chian Yong, Dr. Noor Afifah Said

I, ……....……..……, IC No : ……..…….…….....

- have read the information in the Participant Information Sheet **including information regarding the risk in this study.**
- have been given time to think about it and all of my questions have been answered to my satisfaction.
- understand that I may freely choose to withdraw from this study at anytime without reason and without repercussion
- understand that my anonymity will be ensured in the write-up.

I voluntarily agree to be part of this research study, to follow the study procedures, and to provide necessary information to the doctor, nurses, or other staff members, as requested.

…….	…….
(Signature)	(Date)
…….	…….
Witness (if any)	Researcher
…….	…….
(Signature)	(Signature)
…….	…….
(IC Number)	(IC Number)
……..…	…….
(Date)	(Date)