AKADEMISKA SJUKHUSET

UPPSALA UNIVERSITET

Effects of Replacing Chest X-ray with Lung Ultrasound in Patients Undergoing Thoracic Surgery

A Randomized Controlled Trial

Participant Information and Informed Consent Form

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Study Contact Information

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Information to Study Participants

We want to ask you to participate in a research study. In this document you will receive information about the study and the implications of participation.

What type of project is this and why do we need me?

During your lung surgery, the surgeon will empty one of your lungs of air, causing it to collapse. When the surgery is done, the lung is re-inflated again. To ascertain correct inflation, a chest x-ray is usually performed, usually multiple times. After the surgery you are monitored by health care professionals.

This study's aim is to investigate if chest x-ray can be replaced by an examination with ultrasound. Advantages with ultrasound examination is that it can be performed without transportation from your ward, even your bed, and is free from radiation.

How is the study conducted?

As a patient, you are admitted to the thoracic surgical ward, 50D. You will after having given consent to participation in the study, be randomized to either a group examined with ultrasound, or a group receiving routine x-ray. The health care professionals caring for you will know which group you belong to and will mark your patient documentation accordingly. Apart from the examination of your lungs, we will gather information from various measurements normally collected in the surgical ward, such as blood pressure, pulse, or blood oxygen content.

If you are randomized to the group receiving ultrasound, a specialist nurse will examine you soon after completion of the surgery. Following examinations are performed in your bed in

the surgical ward. During the examination you are asked to remove your shirt (you can still wear breast-support garment). The ultrasound examination takes 3 – 10 minutes. Before leaving Akademiska sjukhuset you will also receive **one** chest x-ray.

If you are randomized to the group receiving chest x-ray, you will be examined soon after completion of the surgery in your bed. Following examinations will be performed by x-ray personnel at a radiology department in the hospital.

Before leaving the hospital, we will ask you to fill out a questionnaire about your experiences regarding the examinations. This questionnaire takes about 15 minutes to complete.

Are there any risks of participating in the study?

The routine care with chest x-ray is a well-established examination which your health care provider is used to interpret. The results from the ultrasound examination will be reported to your doctor by an experienced specialist nurse. This nurse does not directly diagnose you but is instead reporting and consulting your doctor about relevant findings.

Lung ultrasound is not harmful to the body, and you will not be subjected to any permanent harm. During longer periods of ultrasound, a localized heat may be experienced, and you may because of unintended pressure on the skin feel slight discomfort in the area surrounding your surgery. This discomfort is not harmful. All equipment is thoroughly disinfected, however there may be a small risk of transfer of bacteria from the machine onto your skin.

What happens to my data?

The study will collect and register data about you. The information we collect are images from the examination and vital parameters, along with data from your patient journal. This data will be stored as long as the study is running. Data about you will be protected according to the EU data protection act. Your data will be coded in a manner that only researches affiliated with the study can access and be managed in a way that no other parties can de-code or interpret. The study result will be published in a scientific journal and your data will be anonymized so that no connection to you as an individual can be made.

According to the EU:s data protection act, you have the right to access your data and how they are processed in the study, free of charge. You also have the right to correct data that you feel have been invalid. If you request, your data will be deleted, or if you want the collected data to be restricted in any manner.

If your want to access your data, contact the principial investigator Julia Jakobsson (julia.o.jakobsson@akademiska.se, 0736 – 754138). Data protection ombudsman can be reached at telephone 018 - 611 00 00, or e-mail: dataskyddsombud@regionuppsala.se. If you are dissatisfied with how your data are managed, you have the right to subject a formal complaint to the Swedish Agency for Integrity.

How do I receive results from the study?

During the study you have the right to access material and findings that are stored in you patient journal. Apart from ultrasound imaging, no new data will be collected from you. Contact the principial investigator if you have any questions regarding your participation (se below). You also have the right to *not* access the result of this study.

Insurance and reimbursement

Your are insured through your health care insurance that is associated with care in Sweden. No reimbursement will be offered to participants.

Participation is voluntary

Your participation is voluntary and you can at any time choose to discontinue your participation. If you choose not to participate, you will not be obligated to state a reason, and it will not affect your further care or treatment. In order to discontinue your participation, contact the principial investigator.

Responsible for the study

Principal investigator is Julia Jakobsson, specialist anesthesiologist and intensivist, and can be reached at e-mail: julia.o.jakobsson@akademiska.se or telephone: 0736–754138.

Other researchers are:

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Informed Consent Form

I have verbally and written been informed about the study *"The Effects of Replacing Chest X-Ray with Lung Ultrasound for Patients Undergoing Thoracic Surgery"*. I have been able to ask questions and have been given enough time to consider my decision.

I <u>consent</u> access to my patient journal to the study researchers, so that study researchers can interpret and analyze my results in a confidential manner.

I <u>consent</u> to data about me being collected, stored, processed and published conditioned that it is handled confidentially as mentioned in this document.

_____ _____

Signature Name clarification

_____

Date (YY-MM-DD)

I have given you information about this study and handed you a copy of the written informed consent.

_____ _____

Investigator signature Namnförtydligande

_____

Datum (ÅÅ-MM-DD)