

Accuracy of Ultra-Low-Dose CT (ULDCT) of the Chest Compared to Plain Film in an Unfiltered Emergency Patient Cohort

Informed consent form

UP-Chest

(Ultra-Low-Dose CT versus Plain Film in Emergency Department Patients – Chest)

English Version

Version 1.4

24th of April 2019

Informed consent form for participation in the clinical study

Accuracy of Ultra-Low-Dose-CT (ULDCT) of the Chest Compared to Plain Film in an Unfiltered Emergency Department Patient Cohort

Dear participant:

You are invited to participate in the aforementioned study, about which you will be informed in a detailed medical consultation.

Your participation in this clinical trial is voluntary. You can withdraw from the study at any time without any explanation. Refusal to participate or early withdrawal from this trial will not have any adverse effects on your medical care.

Clinical studies are necessary to obtain reliable new medical research results. However, an indispensable prerequisite for conducting a clinical trial is your written consent to participate in this clinical trial. Please read the following text thoroughly as a supplement to the consultation with your physician and do not hesitate to ask any questions.

Please only sign this consent form

- if you have fully understood the nature and procedure of the clinical trial,
- if you are willing to agree to participate, and
- if you are aware of your rights as a participant in this clinical trial.

This clinical trial as well as the patient information and the consent form have been approved by the responsible ethics committee.

1. What is the purpose of this clinical trial?

The purpose of this clinical study is to compare plain film of the chest with a special computed tomography that requires very little radiation dose - only 1/30 of the radiation dose of a standard computed tomography. The objective is to compare the accuracy of the two methods with regard to diagnosis, and thus, their effect on therapeutic decisions.

2. How is this clinical trial conducted?

This clinical study will be conducted at the Department for Radiology and Nuclear Medicine and the Department for Emergency Medicine of the Medical University of Vienna and will have a total of 300 participants.

The following procedures will be conducted for study purposes only:

Since the emergency department has determined the necessity of an X-ray examination of your chest, a chest X-ray has been scheduled for you. In addition to this chest X-ray, this study also provides you with a three-dimensional image of the chest via a special cross-sectional imaging technique (computed tomography), which will be performed with a particularly low radiation dose. This ultra-low-dose computed tomography (ULDCT) will be performed during your current stay in this hospital. Therefore, no additional visit is necessary.

The additional ultra-low-dose computed tomography, within the scope of the study, extends the examination time by a maximum of 30 minutes and the maximum time until the results of all examinations are available is two hours.

3. What is the benefit of participating in this clinical trial?

It is possible that your participation in this clinical trial will not directly benefit your health. However, the computed tomography may provide your attending physician with additional information that may help to give you a more accurate diagnosis, and therefore, better therapy.

If it is confirmed that this special computed tomography provides additional information compared to a plain film of the chest, then this procedure will be used more frequently instead of, or in addition to, simple plain film of the chest in the future. In this way, future patients might benefit from the results of this study.

4. Any risks, complaints or side effects?

Since both examinations (plain film of the chest and ultra-low-dose CT of the chest) are performed with minimal radiation dose, no health risks are expected. Ultra-low-dose computed tomography of the chest has an effective dose of approx. 0.2 mSv, which is roughly equivalent to the radiation dose of a transatlantic flight or one month of natural background radiation. The plain film of the chest has a dose of approx. 0.08 mSv. The radiation exposure is therefore harmless. The examination is performed without contrast agent.

5. What should be done in case of symptoms, side effects and/or injuries?

You must inform your doctor if any symptoms, side effects or injuries occur in the course of the clinical study. In case of serious side effects, you must inform your doctor immediately, if necessary, by telephone. As no medication is administered in this study, no side effects are to be expected.

6. In which cases will the clinical trial be terminated prematurely?

You may revoke your willingness to participate and withdraw from the clinical trial at any time, even without stating your reasons - without incurring any disadvantages for your further medical care.

Your study physician will immediately inform you of any new findings regarding this clinical trial that may be relevant to you. On this basis, you will be able to reconsider your decision to continue your participation in this clinical trial.

However, it is also possible that your study physician may decide to end your participation in the clinical trial prematurely without obtaining your consent first. The reasons for this may be:

- a) You do not meet the requirements for the clinical trial;
- b) Your investigator is under the impression that further participation in the clinical trial is not in your best interest.

7. Data protection and privacy

Regarding the data that is collected and processed about you within the framework of this clinical study, there is a difference between:

- 1) personal data by which you can be identified directly (e.g., name, date of birth, address, imaging data, etc.),
- 2) pseudonymized (encrypted) personal data, in which all information that would allow anyone to directly deduce your identity is replaced by a code (e.g., a number) or made unrecognizable (e.g., in the case of images). As a result, the data can no longer be linked to you without additional information and without disproportionate effort.
- 3) anonymized data, where traceability to your person is no longer possible.

The encryption key is strictly separated from the encrypted data records and exclusively stored at your study center.

Access to your unencrypted data is available to the investigator and other study center staff involved in the clinical trial or your medical care. The data is protected against unauthorized access. In addition, authorized representatives of the sponsor, the Medical

University of Vienna, who are bound to secrecy, as well as representatives of domestic and/or foreign health authorities and the relevant ethics committees, may inspect the unencrypted data if this is necessary or required to verify the proper conduct of the clinical trial.

The data will only be passed on in encrypted or anonymized form. For any publications, too, only encrypted or anonymized data will be used.

Anyone having access to your encrypted and non-encrypted data is subject to the European General Data Protection Regulation, as well as the Austrian adaptations thereof in their current version.

No data will be transferred to countries outside the EU in the context of this clinical trial.

You may revoke your consent to the collection and processing of your data at any time. After your revocation, there will be no further data collected about you. However, the data collected until revocation may be used further within the scope of this clinical study.

Due to the legal regulations, you also have the right to inspect your personal data and the right to correct it if you discover any errors, unless this is likely to make it impossible or seriously impair the conduct of the clinical trial.

You also have the right to file a complaint with the Austrian data protection authority regarding the handling of your data (www.dsb.gv.at).

The expected duration of the clinical trial to examine all 300 patients is 1 year. The duration of the storage of your data beyond the end of the clinical trial is regulated by legal provisions.

If you have any questions regarding the handling of your data in this clinical trial, please contact your study physician first. If necessary, the study physician can forward your request to the appropriate representatives at the Study Center who are responsible for data protection.

Data protection officer of the Medical University of Vienna:
datenschutz@meduniwien.ac.at

Data protection officer of the AKH: datenschutz@akhwien.at

8. Are there any expenses for the participants? Will there be any reimbursement of expenses or remuneration?

Your participation in this clinical trial will not incur any additional costs for you.

You will not receive any reimbursement for your participation in this clinical trial.

9. Discussion of any further questions

If you have any further questions regarding this clinical study, please contact your study physician or his staff. They will also be happy to answer questions concerning your rights as a patient and participant in this clinical trial.

Name of contact person: Ass.-Prof. Priv.-Doz. Dr.med. Paul Apfaltrer, MBA

Available at: +43 1 40400 48930

10. Declaration of consent

Name of the patient:

Date of birth:

I agree to participate in the clinical study *UP – Chest (U*ltra-low-dose CT versus *P*lain Film in Emergency Department Patients – Chest).

Mr./Mrs. informed me in detail and comprehensibly about the clinical study, possible strains and risks, as well as about the nature, significance, and scope of the clinical study, as well as the resulting requirements. In addition, I have read this patient information and consent form, which comprises a total of six pages. Questions that arose were answered comprehensibly and sufficiently by the study physician or his staff. I had enough time to decide. I currently have no further questions.

I will obey the doctor's orders that are necessary for the execution of the clinical study, but I reserve the right to terminate my voluntary participation at any time without any disadvantages for my further medical care.

I explicitly agree that my data collected as part of this clinical trial will be used as described in the "Privacy" section of this document.

I have received a copy of this patient information and consent form. The original remains with the study physician.

.....
(Date and patient’s signature)

.....
(Date as well as name and signature of the study physician)