Official Title of the study: Prospective Multicentric Study of the Patient Radiation Dose During Five Endourological Procedures: Insertion and Replacement of Ureteral Stent, URS, (Mini-)PCNL/ PCNL and ESWL/SWL

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Investigators:

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Research institution: AZ Klina

Ethical committee: AZ Klina / UZA

Local physician-researchers:

1. Dr. Vincent De Coninck, Urologist, AZ Klina

2. Prof. Dr. Stefan De Wachter

I - Necessary information for your decision to take part in this study

Introduction

You are invited to participate in an interventional clinical trial. This means that the treatment proposed to you is slightly different from the usual method, in accordance with the conditions of good medical practice and regardless of your possible participation in this study. We only ask that you allow us to collect data from your medical file that was obtained during a procedure you are undergoing so that we can process it statistically for research purposes. We will not propose any additional procedure for diagnosis or follow-up.

Before you agree to participate in this study, we ask that you familiarize yourself with what this study will entail in terms of organization so that you can make an informed decision. This is called "informed consent".

We ask you to read the following pages of information carefully. If you have any questions, please contact the medical examiner or his or her representative.

This document consists of 3 parts: essential information you need to make your decision, your written consent and appendices in which you will find more details about certain parts of the basic information.

If you participate in this study, you should know that:

- The treatment that the doctor-researcher gives you in accordance with the current recommendations will not change as a result of your participation in this study.
- This clinical study was drawn up after evaluation by one or more ethics committees.
- Your participation is voluntary; there can be no coercion in any way. For participation requires your signed consent. Even after you have signed, you can let the researcher know that you want to stop your participation.
- The data collected as part of your participation is confidential. Publication of the results ensures your anonymity.
- Insurance has been taken out in case you sustain damage as a result of your participation in this clinical study.
- If you require additional information, you can always contact the physician-researcher or a member of his or her team.

Additional information about your "Rights as a Clinical Trial Participant" can be found on page 3.

Objectives and course of the study

The aim of this study is to determine the radiation dose in the patient that is determined during five endourological procedures, one of which you will undergo: insertion or replacement of a ureteral stent, ureterorenoscopy (URS), (mini-) percutaneous nephrolithotomy (PNL/PCNL) and extracorporeal shock wave lithotripsy (ESWL/SWL).

At the beginning of the procedure you are undergoing, the doctor/fluoroscopy technician will adjust the frames per second (= number of photos taken per second). For group 1 this will be between 3-5, for group 2 it will be >5 to 8. You will be automatically assigned to a group. The course of the procedure and the surgeon's habits remain unchanged.

We propose you to participate in this clinical study. We anticipate approximately 870 participants in this study. Your participation in this study will not require any additional time from you (in addition to your treatment).

Description of the risks and benefits

Advantages: You make an important contribution to scientific research and thus ensure a decrease in radiation dose in future endourological procedures. Patients with the lowest settings on the radiation machine probably have a lower radiation dose, but in this group a longer radiation time/fluoroscopy time may be required to achieve the same image quality.
Risks: no. You will need the procedure and the associated use of radiation anyway and no additional interventions will be performed.
As mentioned above, the treatment proposed to you (stent insertion or replacement / URS / PCNL / SWL) and the diagnosis and follow-up procedures are in accordance with good medical practice.

Withdrawal of your consent

Your participation in this study is voluntary and you have the right to withdraw your consent for any reason. You do not have to give a reason for this.
If you withdraw your consent, the data collected up to the time of your termination will be retained. This is to guarantee the validity of the study. No new information will be given to the investigators.

If you participate in this study, we ask that you:

- To cooperate fully for the correct course of the study.
- No information about your state of health, the medicines you are taking or the to conceal symptoms you are experiencing.
- Inform your doctor-researcher if you are suggested to change to another study so that you can discuss with him/her whether you can participate in this study and whether your participation in the current clinical study should be stopped.

Contact

If you require additional information, but also in case of problems or concerns, you can contact the physician-researcher (Dr. Vincent De Coninck) or a member of his/her study team (Urology Secretariat) on telephone number +32 3 650 50 56.
If you have any questions regarding your rights as a study participant, you can contact the ombudsman service at your hospital on the telephone number. If necessary, the ombudsman service can put you in touch with the Ethics Committee.

II - Additional information

Additional information about the protection and rights of the clinical trial participant

Ethical committee

This study was evaluated by an independent ethics committee. The ethics committees are tasked with protecting individuals who participate in clinical trials. They check whether your rights as a patient and as a participant in a study are respected and whether the study is scientifically relevant and ethically responsible.
The ethical committees issue an opinion on this in accordance with the Belgian law of 7 May 2004.
Under no circumstances should you regard the positive advice of the Ethics Committees as an incentive to participate in this study.

Voluntary participation

Please feel free to ask any questions you find helpful before signing. Take the time to talk to a counselor about it, if you wish.

You have the right not to participate in this study or to discontinue this study without giving a reason, even if you have previously agreed to participate in this study. Your decision will in no way change your relationship with the physician researcher and the continuation of your therapeutic treatment.

If you agree to participate in this study, you will sign the consent form. The physician-researcher will also sign this form to confirm that he has provided you with the necessary information for this study. You will receive the copy intended for you.

Costs associated with your participation

The investigators have agreed to reimburse the hospital for the time spent by the physician researcher and his team on this study. You will not receive any compensation for your participation in this study. However, your participation will not entail any additional costs for you.

Confidentiality guarantee

Your participation in the study means that you agree that the physician-researcher collects data about you and that the sponsor of the study uses it for research and in the context of scientific and medical publications.

Your data will be processed in accordance with the European General Data Protection Regulation (GDPR) and the Belgian Legislation on the protection of natural persons with regard to the processing of personal data. Dr. Vincent De Coninck is the controller of your data.

You have the right to ask the physician-researcher what data he has collected about you and what it will be used for in the context of the study. This data relates to your current clinical situation, but also to your medical history and the results of examinations carried out for the treatment of your health according to the current standard of care. You have the right to view this data and to have corrections made if it is incorrect.

The physician-researcher is obliged to treat this collected data confidentially.

This means that he undertakes never to reveal your name in the context of a publication or a conference and that he will encrypt your data (your identity will be replaced by an identification code in the study) before passing them on to the database manager (Dr. Vincent De Coninck, AZ Klina).
The physician-researcher and his team will be the only persons able to establish a link between the transferred data and your medical record throughout the entire clinical study.
The personal data transferred does not include a combination of elements that could identify you.
The research data manager appointed by the client cannot identify you based on the data transferred. This person is responsible for collecting the data collected by all physician-researchers participating in the study and for the processing and protection of that data in accordance with the Belgian law on the protection of privacy.

To check the quality of the study, your medical file may be inspected by persons bound by professional secrecy, such as representatives of the ethics committees, the sponsor of the study or an external audit agency. This can only happen under strict conditions, under the responsibility of the physician researcher and under his/her supervision (or one of his/her research assistants).
The (coded) research data can be passed on to Belgian or other regulatory authorities, to the ethics committees, to other doctors and/or institutions that collaborate with the client.
They may also be transferred to other sites of the client in Belgium and in other countries where the standards for the protection of personal data may be different or less strict. This always happens in coded form as explained above.

Your consent to participate in this study therefore also means that you agree that your coded medical data will be used for the purposes described in this information form and that they will be transferred to the above-mentioned persons and/or institutions.

The client undertakes to use the collected data only in the context of this study.

If you withdraw your consent to participate in the study, the coded data already collected before your withdrawal will be retained. This guarantees the validity of the study. No new information will be passed on to the client.

If you have any questions about how we use your data, you can always contact your doctor-researcher. The data protection officer of the research center is also at your disposal.

Finally, if you have a complaint about the processing of your data, you can contact the Belgian supervisory authority that monitors compliance with the basic principles of personal data protection:

The Belgian supervisory authority is called:
Data Protection Authority (GBA)
Drukpersstraat 35,
1000 Brussels
Tel. +32 2 274 48 00
e-mail: contact@apd-gba.be
Website:www.dataprotectionauthority.be

Insurance

In a clinical interventional study, the only possible risk is a problem with the measures taken to protect the confidentiality of your personal data.

Even if there is no fault, the client is liable for any damage that you as a participant - or in the event of death, your beneficiaries - incur and that is directly or indirectly attributable to participation in this study. For this purpose, the client has concluded an insurance contract through University of Antwerp.

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III Informed consent

Participant

I declare that I have been informed about the nature, purpose, duration, possible benefits and risks of the study and that I know what is expected of me. I have taken note of the information document and its appendices.
I have had plenty of time to think and talk to a person of my choosing, such as my GP or a family member.
I was able to ask all the questions that came to mind and I received clear answers to my questions.
I understand that my participation in this study is voluntary and that I am free to discontinue my participation in this study without harming my relationship with the therapeutic team responsible for my health.
I understand that data will be collected about me during my participation in this study and that the physician-researcher and the client ensure the confidentiality of this data in accordance with relevant European and Belgian legislation.
I consent to the processing of my personal data in accordance with the modalities described in the section on ensuring confidentiality on page 4. I also consent to the transfer to and processing of my encrypted data in countries other than Belgium.

I have received a copy of the Participant Information and Informed Consent.

Name	Surname	Date	Signature

Physician-researcher

I, the undersigned, physician-researcher, declare that I have provided the necessary information regarding this study orally and that I have provided a copy of the information document to the participant.
I confirm that no pressure was placed on the participant to consent to taking part in the study and I am willing to answer any additional questions you may have.

I confirm that I work in accordance with the ethical principles stated in the "Declaration of Helsinki", the "Good Clinical Practice" and the Belgian law of 7 May 2004 on experiments on the human person.

Name	Surname	Date	Signature