Information sheet for the patient (or his/her legal representative)

Protocol Number S59182

Flemish Collaborative Glomerulonephritis Group Database

Contacts

Sponsor : Universitaire Ziekenhuizen Leuven

Principal Investigators (members of the steering committee FCGG):

- Tom Dejagere, Department of Nephrology, Jessa, Hasselt
- Amélie Dendooven, Department of Anatomical Pathology, UZ Antwerpen
- An De Vriese, Department of Nephrology, AZ Sint-Jan, Brugge
- Caroline Geers, Department of Anatomical Pathology, UZ Brussel
- Mark Helbert, Department of Nephrology, ZNA, Antwerpen
- Rachel Hellemans, Department of Nephrology, UZ Antwerpen
- Wim Laurens, Department of Nephrology, AZ Nikolaas, Sint-Niklaas
- Evelyne Lerut, Department of Anatomical Pathology, UZ Leuven
- Bart Maes, Department of Nephrology, AZ Delta, Roeselare
- Lissa Pipeleers, Department of Nephrology, UZ Brussel
- Ben Sprangers, Department of Nephrology, UZ Leuven
- Jo Van Dorpe, Department of Anatomical Pathology, UZ Gent
- Steven Van Laecke, Department of Nephrology, UZ Gent

You are invited to participate in a registry study. Before you decide to participate, it is important that you understand the reason for this study is and what it involves. Please take whatever time you need before deciding to participate or not. Discuss, if you so wish, your participation with your family, your friends or your doctor.

The patient information sheet and consent form has two parts:

- Part 1 explains to you the purpose of the study and what will happen if you decide to take part
- Part 2 explains in full detail what your rights are as a participant in a study

This document provides information about the study. Please read this information sheet and consent form carefully and ask all questions you might have with regard to this study so that you can make an informed decision whether or not to participate.
Participation in this study is voluntary and if you should decide not to participate in this study, your future medical care will not be affected in any way. Whenever and whatever questions you may have while reading this document, please ask your doctor or nurse to explain to you the words or information that you do not understand. If, after reading this document, you decide to take part in the study we will ask you to sign the information and consent form. You will receive a copy of this document for your records. When you agree to participate we will also inform your family doctor.

The execution of this study has been approved and will be monitored by the Ethics Committee, namely “Commissie Medische Ethiek van de Universitaire Ziekenhuizen KU Leuven” and the local ethics committee of your center. These committees exist of an independent panel of doctors, nurses and non-medical staff that evaluates the protocol and the risks involved for the participants. The approval by these ethical committees should not be taken as inducement to participate in the study.

PART 1 (Information about the study)

BACKGROUND INFORMATION

Introduction

Chronical kidney disease affects more than 10 % of the population. Causes for acute and chronic kidney disease are diverse and can be, amongst others, damaged blood vessels around the kidneys, glomerulonephritis (inflammation of the kidney filtering cells), diabetes, hereditary disorders, renal toxicity…. In some patients the kidney disease progresses into severe kidney failure that needs to be treated with renal replacement therapy (dialysis, peritoneal dialysis or kidney transplant).
A lot of factors are to be considered with regard to the onset as well as the progression of renal disease (genetic factors, blood pressure, obesity…). The consequences of a decreased renal function are not limited to a disrupted salt and water balance of the body. A decreased renal function also has an important effect on the other body organs such as the cardiovascular system, bone marrow, hormonal balance, the brain and the bone The knowledge and understanding of factors and mechanisms responsible for the onset and the progression of renal disease and related complications increase steadily. However, there still are a lot of ambiguities and often it so that new understandings generate new questions. We are convinced that a better knowledge of these factors and mechanisms offers possibilities towards better prevention and treatment of kidney disease

Purpose of the research

By developing a database that contains information about patients undergoing a kidney biopsy in Flanders, the participating centers want to obtain information with regard to the occurrence of renal disorders.

PROCEDURE OF THE STUDY

Which data will be included in this database?

- Basic information such as coded identity, age (date of birth), gender, race, medical history will be registered
- Histological diagnoses (based on examination of the kidney biopsy under a microscope) and clinical diagnoses (based on symptoms and abnormalities in the blood and urine)
- Biochemical parameters such as renal function, loss of protein, urine analysis, immunological tests (that check the functioning of the immune system: a. o. antibodies and complement), and other biochemical evaluations (blood and urine tests) executed within the context of nephrological diagnostics, will be included in this registry database.
- No additional blood samples or other examinations will be required with regard to this study which is only concerned with the registration of these data in a central database.

POSSIBLE RISKS AND DISCOMFORTS

What are the risks involved with regard to the procedures of this clinical study?

As there are no additional procedures required by this study, there are no risks involved in participating in this study.

Upon initial entry in the database, the patient will be assigned a unique identifier. Consequently, as the data are processed they are anonymized by a code in order to guarantee patient confidentiality. The database will also be password protected and the entering of the data will only be trusted to a limited amount of persons. In each center the participating nephrologists will have a view-only access to the database, which means that they will be able to view the patients that they enrolled (but they will not be able to make changes to the data). In the centers where the data are entered into the database (UZ Antwerpen, UZ Gent and UZ Leuven) 1 nephrologist and 1 nephro-pathologist at the time will have access to the database and permission to enter and or modify the data. Also 2 coders per center will be able to enter data. Furthermore 2 administrators per center (1 administrator appointed by the NBVN (Nederlandstalige Belgische Vereniging voor Nefrologie) Registry Work Group and 1 administrator appointed by the steering committee of the Flemish Collaborative Glomerulonephritis Group) will also have access to the entire database and will be able to make modifications). The database will be managed by the NBVN under supervision of the steering committee of the FCGG. New patients will be included until 10,000 patients are accounted for in the registry, or until 10 years have passed, whichever comes first.

BENEFITS TO TAKING PART IN THIS STUDY

Will I benefit from participating in this study? Will others benefit from it?

Participating in this study does not guarantee you any direct benefits. However, the acquired knowledge thanks to your participation may benefit patients with Chronical Kidney Disease in the future.

PART 2 (Rights of the participant in this study)

CONFIDENTIALITY / PROTECTION OF PERSONAL DATA

We will take following steps to keep information about you confidential and protect it from unauthorized disclosure:

Your name or your initials will be removed from your file. The collected data from the study will be coded with a patient identifier, only disclosing your full date of birth and gender.

You may rest assured the all data about your person, acquired during this investigation, will be treated with highest confidence and that unauthorized personnel will have no access to your data.
The results of this study may be used for scientific publications, but even so the results cannot be linked to your person.
Your personal data will be kept confidential in compliance with medical secrecy and the Belgian law of December 8, 1992 concerning the protection of private life, and the law of August 22, 2002 concerning the patient's rights.
Furthermore, at all times you will have the right to access, consult or correct your personal data file in this study.

POTENTIAL COSTS / REMUNERATIONS

What will be my personal cost with regard to this study?

The study will not incur any additional expenses to you, nor will you be compensated for your participation in this study.

Voluntary participation

Your participation in this registry is voluntary. If you decide to participate in this study you are still free to withdraw from the study at any time without any further explanation. Your decision to participate or not will not affect your future medical care or harm your relationship with your physician. Please take your time before deciding whether to join or not.

Insurance

<u>Insurance in accordance with the law of May 7, 2004</u>
The risk resulting from this experiment is covered by article 29 of the Belgian law of May 7, 2004 with regard to experiments on the human person, that requires the sponsor to assume, even without fault, liability for damage caused to the participant or its successors and linked directly or indirectly to this experiment. In this context the sponsor has taken out an insurance contract with the insurer mentioned here below.
The address data of the insurance are : Van Breda Risk & Benefits (Amlin Europe NV) - Plantin en Moretuslei 297, 2140 Antwerpen - Polisnummer: 299.053.700.

Conclusion

If you should have, as a result of the above information, any further questions with regard to this investigation, you can contact your nephrologist.

If you decide to participate in the investigation, please indicate your agreement by signing the next page. Signing will not commit you to anything, but is merely to indicate that you have received this information and that you understand and are aware of what will be expected of you with regard to the investigation.

You will receive a copy of this form for your records. If you agree to participate we will also inform your family doctor of your participation.

Contact persons: Staff members of the Nephrology department of your hospital center, or Professor Ben Sprangers (UZ Leuven – principal investigator)

Participating centers and conducting investigators (Nephrologist)

AZ Delta Roeselare	Bart Maes (051237284)
AZ Glorieux Ronse	Anne-Marie Bogaert (093648565)
AZ Groeninge Kortrijk	Marc Decupere (056323370)
AZ Maria Middelares Gent	Pascale Bernaert (092468800)
AZ Monica Antwerpen	Kristien Huysmans (032402814)
AZ Nikolaas Sint-Niklaas	Wim Laurens (037602256)
AZ Sint-Blasius Dendermonde	Anja De Rycke (052252666)
AZ Sint-Jan Brugge	An De Vriese (050452202)
AZ Sint-Jozef Malle	Annemie Woestenburg (033802721)
AZ Sint-Lucas Brugge	Liza Reyns (050365905)
AZ Sint-Lucas Gent	Jan Donck (092246550)
AZ Turnhout	Miranda Zeegers (014444432)
GZA Sint-Augustinus Antwerpen	Johan Scharpé (034433630)
GZA Sint-Vincentius Antwerpen	De Clippeleir Nele (032852038)
H.-Hartziekenhuis Lier	Kurt Vandepitte (034913036)
Imeldaziekenhuis Bonheiden	Wim Lemahieu (015505118)
Jan Yperman Ziekenhuis Ieper	Hilde Vanbelleghem (057357182)
Jessa Ziekenhuis Hasselt	Tom Dejagere (011309720)
Kliniek Sint-Jan Brussel	Joris Vanparys (022219905)
Onze-Lieve-Vrouwziekenhuis Aalst	Bart Denys (053724383)
Sint-Trudo Ziekenhuis Sint Truiden	Domien Peeters (011699624)
UZ Antwerpen	Rachel Hellemans (038213421)
UZ Brussel	Lissa Pipeleers / Peter Janssens (024776055)
UZ Gent	Steven Van Laecke (093325861)
UZ Leuven	Ben Sprangers (016344580)
Ziekenhuis Oost-Limburg	Luc Verresen (089326532)
ZNA Nierkliniek (Stuivenberg en Middelheim)	Mark Helbert (032804188)

Authorization form for participation in the Flemish Collaborative Glomerulonephritis Group database

I have been adequately informed about the investigation. I have read the written information carefully. I have had a chance to ask questions about the investigation. I have received satisfactory answers to my questions. I have had the opportunity to consider my participation in the study carefully. I have the right to withdraw from the study at any time without having to give a reason.

I agree to participate in the investigation

Patient name and first name: ……..

Legal representative name and first name :…….

Date of birth :…….

Signature :…….

Date :……..

I, the undersigned declare that the above mentioned person has been provided with all the necessary information about the investigation, both written and verbal
He/she also confirms that if the above mentioned person chooses to prematurely leave the study, this will be of no influence on the care that the patient is rightfully entitled to.

Name and first name :……..

Function :……..

Signature :……..

Date :……