Patient information and consent form including data privacy statement

Registry on epidemiology, diagnosis and therapy of C3 glomerulopathies and immunecomplex-mediated MPGN

Short title: Clinical C3G and MPGN Registry

Principal investigator: Prof. Dr. med. Bernd Hohenstein
Division of Nephrology
Department of Internal Medicine III
University Hospital Carl Gustav Carus
at the Technischen Universitaet Dresden
Fetscherstrasse 74, 01307 Dresden
Germany
Phone: +49 351 458 4233

Study site:

(stamp)

Investigator: _____

Phone: _____

Patient‘s number: _____

Dear patient.

We hereby would like to ask for your informed consent to participate in the clinical registry study consecutively desribed.

Clinical studies are necessary to generate or expand knowledge about disease in man. The subsequently described clinical study received a positive assessment by the responsible local ethics committee. This open, clinical registry study aimes at the inclusion of all patients fulfilling the corresponding inclusion criteria. The registry will be provided as Internet-based platform, thereby enabling inclusion by centres from inside and outside of Germany. This study was initiated and organised by the Division of Nephrology, Department of Internal Medicine 3 at the University Hospital Carl Gustav Carus, Dresden, Germany.

Your participation in this clinical study is voluntarily. Therefore, you will only being included after you gave your written informed consent. In case of your decline to participate in this clinical study or a later withdrawal of your consent, you will will not experience any drawbacks.

You had already been approached with respect to this study. Subsequently, we would like to illustrate to you the aims and time course of this study. Please do not hesitate to ask and discuss all points that need further clarification. You will have enough time for consideration to decide about your participation.

1. Why will this study be conducted?

Based upon the growing knowledge of loss is an mechanism is of distinct inflammatory kidney diseases (glomerulonephritis), a new subgroup of glomerulonephritides was defined in 2010. This group, the so-called C3 glomerulopathies (chronic progressive changes of glomeruli, filter unit of the kidney) as well as the distinct (formerly sub-summarized), immunologically-mediated membranoproliferativen Glomerulonephrits (MPGN; desibing characteristic disease related changes of glomeruli) are orphan diseases, occurring with a frequency of 1-2 per million per year.

Due to the novelty of the definition and orphan type of the disease, knowledge about the clinical time course and the optimum diagnostic procedures are limited. A larger summary of clinical time courses including comprehensive diagnostic findings is lacking. Until today, there exists no reliable or validated therapy.

Therefore, improved knowledge about this disease entity can only be established via a central assessment of a large number of cases, including their diagnostic findings and clinical time course. This knowledge will provide the necessary basis for the testing of specific therapeutic options in further clinical trials.

2. How is the planned time course of the study? Are there any specific considerations?

Following your consent to participate in this clinical registry the following findings will be assessed once or in regular follow-up visits every 3-12 months. All diagnostics will be based on analyses initiated by your nephrologist and will not be initiated by this study (this also includes laboratory assessements, which will not be ordered during this study).

Once:
At diagnosis: age, ethnicity, estimated kidney function (eGFR), proteinuria, presence of nephrotic syndrome (a combination of proteinuria, protein depletion of the serum, hypercholesterolemia and swelling of the joints (edema)), presence of increased blood pressure, family history of this disease, presence of secondary causes, current medication, findings of the renal biopsy, evaluating pathologist, written final report.

On a regular basis:
Complement diagnostics after diagnosis: Presence of analysis of the complement system (a part of the immune system involved in the origin of the disease) including findings, presence of genetic diagnostics of known genes of the complement system involved in the origin of the disease including findings, autoantibodies (proteins directed against distinct parts of the complement system) that are causative for the disease
Clinical course: Change of renal function over time since diagnosis, proteinuria, time until 50% decline of renal function or doubling of serum creatinine (a protein indicating kidney function), current medication, initiation of dialysis therapy, time until dialysis, kidney transplantation (yes/no), if yes: recurrence of the disease after transplantation (yes/no), after how many months, remarks
Therapy: Was any therapy initiated (yes/no), is yes supportive and/or immunomodulation using XY, efficacy of therapy.

In addition, we would like to ask you once for providing blood samples (total approx. 30ml), which will be frozen for later analysis of the complement system. We would also like to ask for a urine sample, which will also be frozen for later analysis of proteins or components of the complement system. Your participation in this study will only take a few minutes. Blood - and urine sampling is voluntarily and your refusal will not exclude your participation.

3. Will I have a personal benefit from my participation?

By participating in this registry study you will not have a predictable personal health benefit. However, we are aiming at the subsequent development of clinical trials. Therefore, you might have a benefit from the later development of therapeutic approaches for this disease.

4. Which risks will I take with my participation?

The risk of this study occurs due the drawing of the defined blood samples during your regular medical follow up. The amount of blood will be 30mL. The necessary blood withdrawal will take place during your routine follow-up, usually a separate vein puncture will not be necessary. Apart from a short discomfort due to the vein puncture limited bleeding with the consequence of a small bruise ("hematoma") might occur, which will vanish within a few days. Some persons might show dysregulation of the circulation, even though the drawn amount of blood is very small. To avoid such reactions, blood withdrawal will preferentially performed in a lying position. Of course, our staff will take measures in case you will show such a reaction (for instance rainsing of the legs). Other risks such as infections, thrombosis or injury of adjacent tissues or nerves caused by the needle are very rare (especially due to a sinle puncture) and practically excluded with a trained staff.

Please inform your study team about all complaints, diseases or injuries which occur during the time course of this clinical study. You will find the corresponding contact information on the front page of this patient information.

5. Who cannot participate in this study?

Children and adolescents under age of 18 cannot particitpate in this study.

5. Will my participation in this study generate personal costs? Will I receive a financial compensation?

Your participation in this clinical study will not cause any costs. You will not receive a financial compensation for your participation.

6. Will I be able to stop my participation prematurely?

You will be able to stop your participation anytime, whithout giving reasons. This will not cause to any drawbacks with respect to your medical therapy.

7. What will happen with my personal data?

During this clinical registry study, your medical findings and personal information will be collected in your personalised file in written or electronic form. During this clinical study, all data will additionally being saved in a secured electronic database system using an internet-based electronic form. All this data will be pseudonymised and later on evaluated in anonymous form. The time of data storage will not exceed 30 years.

Pseudonymised means that a number or a letter code, potentially also using your date of birth, will be used instead of names or initials. Therefore, only your local investigator will be able to link your data with your person.

Anonymised means that no conclusions can be made on your individual ID.

Data will be stored on servers at the Technische Universitaet Dresden, Germany, and protected against unauthorized access. Access to this data will be restricted to the principal investigator or his personally authorized sub-investigators. Following anonymization data will be analysed together with the institute for Medical Biometry and Statistics at the TU Dresden and the Coordination Center for Clinical Studies at the TU Dresden.

8. What will happen with my samples (blood and urine)?

Pseudonymised blood- and urine samples will be collected centrally at the coordinating study center in Dresden. Depending on the further developments and knowledge the samples will be used to expand on mechanistic interactions or causes of the disease (with respect to the complement system), which are currently unknown.

All blood samples will exclusively being used for this clinical study, will be stored for a maximum of 15 years and will be destroyed thereafter. In case you withdraw your consent to participate in this study, blood and urine samples will be anonymised.

9. Whom may I ask further questions?

Consultation at the study site

You will always have the opportunity for a further consultation with the responsible investigator named on page 1 or an sub-investigator.

Informed Consent incl. Data Privacy Statement

.....

Patient's name (printed letters)

born ..... patient no. .....

Is was informed during an conversation with

.....

Physician's name (printed letters)

about this clinical registry study in an elaborate and comprehensible way including the content, meaning, risks and consequences of this study. I have read and understood the patient's information including the printed data privacy statement. I had the chance to discuss the course of this clinical study with the investigator. All questions had been answered sufficiently.

Space for documentation of additonal questions from the participant oder other aspects of the informational conversation:

I had enought time to make a decision.

I am aware that I can withdraw (in oral or written form) without explanatory statement my consent for this study anytime and will not experience any drawbacks with respect to my medical treatment.

Data Privacy Statement

I am aware that during this clinical study personal data, especially personal medical findings, will be assessed, stored and evaluated. The utilization of health realted data will meet legal requirements and presumes my voluntarily given informed consent to participate in this clinical study, meaning that I cannot participate in this study without my subsequent informed consent.

1. Hereby, I declare my consent for the study specific inquiry and storage of personal data, especially personal health data and ethnicity, in written form and electronic storage devices at the coordination center for clinical studies at the Technische Universitaet Dresden, Dresden, Germany, in encrypted form (without the use of names and initials). As required, pseudonymised data can be transfered to the principal investigator or an assigned institution for scientific evaluation.

2. I agree that authorized and sworn to secrecy commissioners of responsible surveillance authorities including the ethics committee of the Medical Faculty at the Technische Universitaet Dresden, Dresden, Germany, get access to my personal data stored by the investigator, especially including personal health data, as far as this is necessary for the inspection of the legal execution of this study. With respect to these inspections I aquit the investigator from his professional discretion.

3. My consent to collect and process my personal data, especially personal medical findings, is revocable. I was informed that I can stop my participation in this clinical study anytime. Following the withdrawal of my consent to participate in this clinical study, all my data have to be deleted and blood- and urine samples have to be anonymized, except I give my consent for the further use of data in an anonymized fashion.

I hereby give my informed consent to voluntarily participate in the above-named clinical registry study.

I convey my blood and urine samples and agree with the use of my samples in pseudonymized fashion as described above. The authorization for the pseudonymized usage can be withdrawn anytime with effect for the future. Subsequently, my samples will be used in anonymized fashion.

I have received a copy of the patient's information and consent form. One copy will remain at the study site.

.....

Printed patient's name

.....	.....
Date	Patient's signature

I conducted the patient's information and I received patient's informed consent.

.....

Printed investigator's name

.....	.....
Date	Investigator's signature