Information for Patients
on processing of personal data
Information for patients older than 15 years and their caregivers

As preparation for a verbal explanation delivered by the attending physician.

NPC-2016 Registry

Patient: _____ Date of birth: _____

Dear Patient, dear Guardian,

Please allow yourself enough time to read the information and consent form and discuss it with the attending physician.

Your child has been diagnosed with nasopharyngeal carcinoma.

Nasopharyngeal carcinoma (abbreviation: NPC) is a very rare, **malignant tumour** commonly found in the pharynx and throat.

The tumour cells can grow into the base of the skull, where they can cause serious neurological damage and disrupt the hormonal system. The cervical lymph nodes can be affected by spread through lymphatic vessels, as well as bones, lungs and liver due to metastasis through the blood.

Depending on the extent of the disease, the tumour can be classified in stages I to IV. Stage I has the best chances of full recovery after treatment. Most patients are already at an advanced stage when they are diagnosed (stage III or IV). Stage IV is a large, locally advanced tumour involving lymph nodes of the neck, which may have already given out tumour cells into the bloodstream. In these cases, metastases can be detected in diagnostic imaging tests.

How can nasopharyngeal cancer be treated?

In the past, nasopharyngeal carcinoma was treated exclusively with radiation therapy. The recovery chances of patients in the more favourable stages treated with sole radiation therapy amounted to around 75%, while the healing rate for patients in stages III and IV treated the same way was very low. In the literature healing rates of as low as between 30% to 50% were reported.

The NPC-91 and NPC-2003 trials conducted by the German Society of Paediatric Haematology and Oncology (GPOH) showed that the chances of recovery with combined treatment consisting of chemotherapy, radiotherapy and maintenance therapy with Interferon-beta significantly improves the process with response rates of over 90%.

Therapy usually begins with chemotherapy, which is supposed to decrease the size of the tumour so that local radiation therapy can be more effective. In addition, the occurrence of metastases can be prevented and existing metastases destroyed. A combination of the cytostatic drugs cisplatin and 5-fluorouracil is generally used. These are administered at three-week intervals over a total period of three months.

Following initial chemotherapy, a combined chemo- and radiation treatment is considered standard today. The combination of radiation therapy with chemotherapy increases the effectiveness of radiation. The irradiation period is usually six weeks.

Drug maintenance therapy with interferon beta following radiation therapy was administered in the GPOH NPC-91 and NPC-2003 studies for a period of six months. The aim of interferon treatment is to destroy the tumour cells that may have survived chemotherapy and radiation therapy. Interferons have a diverse anti-tumour effect, especially in NPC. Interferon is able to destroy tumour cells directly or indirectly via the stimulation of the immune system. A detailed explanation of the medical treatment and radiotherapy, their effects and side effects will be done in the clinic by the oncologists or radiotherapists responsible for the task.

The Nasopharyngeal Cancer Study Group (NPC):

Since nasopharyngeal carcinoma is a rare disease and no patient should suffer due to the rarity of his/her condition, the Nasopharyngeal Carcinoma Study Group was formed within the German Society of Paediatric Oncology and Haematology (GPOH). The task of the study group is to provide consistent recommendations that reflect the current state of science in the diagnosis and treatment of children and adolescents with nasopharyngeal carcinoma and also to further improve the treatment of the disease through scientific investigations. Thus, through the above-mentioned treatment studies (NPC-91 and NPC-2003) the chances of recovery of those patients affected with the disease in recent years have been significantly increased, while the treatment side effects have been reduced.

Objectives of the NPC Registry:

In the NPC-2016 registry, the medical data of patients with nasopharyngeal carcinoma are stored in a central database. The aim is to gain new insights into the origin, as well as the optimal diagnosis, treatment and aftercare of these very rare tumours through national and international cooperation so the patients and their physicians can benefit from them as quickly as possible.

The registry also offers the option of standardising important diagnostic measures and to improve the quality of the diagnosis through central re-evaluation. Nuclear medical diagnostics and X-ray diagnostics are not binding and require the specification of individual indications for treatment. On the basis of the collected data, we can advise the treating physicians if necessary. Therapy decisions are made by your attending physician and are completely independent of your child's participation in this registry.

Structure of the registry:

Detailed disease and therapy data are centrally documented and evaluated. The documentation of the patient data and findings is stored in a central database and overseen by the study team of the registry in Aachen. The registry in Aachen is where all the cooperating clinics report their patients' medical records. The study team and the study-team management are always available to your attending

physicians for any questions regarding this rare disease. In order to ensure there is no confusing information, duplication of data and similar misunderstandings, the information is passed on together with the personal details (name, first name, date of birth, name of treating clinic). Before analysing the data, these identification features such as name and address are replaced by a number. This is called pseudonymisation of data. The collected data are documented and evaluated in full respect of medical confidentiality and data protection laws. Medical confidentiality is required in accordance with § 203 of the German Civil Code. The persons who disclose patient data are relieved of their duty of confidentiality only to the extent shown and for the aforementioned purposes. If necessary, personal data will only be passed on to the reporting centres listed below. They are only available to the treating physicians and their employees, who in turn are subject to secrecy and privacy rules.

NPC-2016 Registry:

Prof. Dr. med. Udo Kontny
Principal investigator
Division of Paediatric Haematology, Oncology and Stem Cell Transplantation
Department of Paediatrics
University Hospital RWTH Aachen University
Pauwelsstr. 30
D-52074 Aachen

In cooperation with the nationwide German Childhood Cancer Registry, oncological data for patients in Germany are also recorded in the respective regional state cancer registries of the patient's place of residence. An agreement was reached between the German Childhood Cancer Registry and the relevant state cancer registries that the German Childhood Cancer Registry forwards the medical records of the child to the respective state cancer registry in accordance with the state cancer registry laws. Only few people have access to the confidential data containing the names of the patients. These are subject to medical confidentiality and data protection laws. The data are pseudonymised immediately after collection, that is, each patient is assigned a national registry number, without the possibility to match the name of the patient with the number that was assigned.

German Childhood Cancer Registry: (applies only for patients in Germany)

Head: PD Dr. P. Kaatsch
Institute for Medical Biometry, Epidemiology and Computer Science (IMBEI)
University Medical Centre Mainz
D-55101 Mainz

Post-treatment registers:

Late Effects Surveillance System, LESS-Working Group

Prof. Dr. med. Thorsten Langer
Late Effect Surveillance System (LESS)
University Hospital Schleswig-Holstein, Campus Lübeck
Department of Paediatrics, Paediatric Oncology and Haematology
Ratzeburger Allee 160, D-23538 Lübeck
(Central Late Effects Surveillance Center of the German Society of Paediatric Oncology and Haematology, GPOH)

Quality of life and long-term follow-up study (Lebensqualität und Spätfolgenstudie PEDQOL)

Dr. med. Gabriele Calaminus
Department of Paediatric Haematology and Oncology
University Hospital Bonn, Adenauerallee 119, D-53113 Bonn
Central Office For Recording The Quality Of Life And Long-term Sequelae (Zentrale zur Erfassung der Lebensqualität und von Spätfolgen)

Reference facilities:

Reference Centre for Pathology

Prof. Dr. med. Christian Vokuhl
Institute of Pathology, Division of Pediatric Pathology, University Medical Centre Bonn, Venusberg-Campus 1, Building 62, Room 116, D-53127 Bonn

Radiology Reference Centre

Prof. Dr. med. Gundula Staatz
Division of Paediatric Radiology, Department of Diagnostic and Interventional Radiology, University Medical Centre Mainz, Langenbeckstr. 1, D-55131 Mainz

Nuclear Medicine Reference Centre

Prof. Dr. med. Felix M. Mottaghy, Clinic for Nuclear Medicine
University Hospital RWTH Aachen, Pauwelsstr. 30, D-52074 Aachen

EBV Virology Reference Centre

Dr. rer. nat. Dipl.-Biol. Wolfram Puppe
Hannover Medical School, Institute of Virology, Carl-Neuberg-Str. 1,
D-30625 Hannover

EBV-specific CTL Reference Centre

Prof. Dr. med. Tobias Feuchtinger
Dr. von Haunersches Kinderspital, University Hospital Munich
Lindwurmstr. 2a, D-80337 Munich

Analysis of DPD Exon 14 Skipping Mutation

Prof. Dr. Ingo Kurth
Institut für Humangenetik, Uniklinik RWTH Aachen
Pauwelsstr. 30, D-52074 Aachen

Radiotherapy Reference Centres

Prof. Dr. med. Hans Christiansen
Department of Radiation Therapy and Special Oncology, Hannover Medical School
Carl-Neuberg-Str. 1, D-30625 Hannover

Prof. em. Dr. med. Günther Gademann
University Hospital Magdeburg
Leipziger Str. 44, D- 39112 Magdeburg

Prof. Dr. med. Michael Eble
Department of Radiation Oncology and Radiotherapy, University Hospital RWTH Aachen, Pauwelsstr. 30, D-52074 Aachen

Prof. Dr. med. Beate Timmermann
Department of Particle Therapy, University Hospital Essen, Hufelandstraße 55, D-45147 Essen

Head and Neck Surgery

Prof. Dr. med. Jens Peter Klußmann
Department of Otorhinolaryngology, Building 23
Kerpener Str. 62, D-50937 Köln

Accompanying Research and Biobanking Material:

In order to further investigate the cause and development of nasopharyngeal cancer and to develop new, more effective treatments, it is of great importance to carry out accompanying studies on the biomaterial acquired from the patients. Examples of biomaterials include tumour samples, blood samples and throat washing samples. Under the coordination of the register, biomaterial will be forwarded to the following cooperation partners:

Prof. Dr. med. Henri-Jacques Delecluse
Pathogenesis of infection-related tumours
German Cancer-Research Centre (DKFZ)
Department of Tumour Virology
Im Neuenheimer Feld 242, D-69120 Heidelberg

Prof. Dr. med. Uta Behrends
Children's Hospital Munich Schwabing,
Klinikum rechts der Isar
Technical University of Munich and
Klinikum Schwabing of StKM GmbH,
Kölner Platz 1, D-80804 Munich

Prof. Dr. med. Ruth Knüchel Clarke / Prof. Dr. rer. nat. Edgar Dahl
Centralized Biobank of the Medical Faculty of the RWTH Aachen University
Institute of Pathology, University Hospital RWTH Aachen
Pauwelsstr. 30, D-52074 Aachen

The material is a tumour sample that fell within the framework of the necessary operative tumour biopsy or in the rare case of a tumour excision. In addition, we would like to ask you for your consent so that a small amount of blood and pharyngeal wash water for research purposes can be obtained. The blood collection takes place only in the context of necessary medical interventions, without additional risk for your child. The amount of blood depends on the age of your child, for a teenager that would be about 25 ml (about 2.5 tablespoons) of blood. In order to obtain throat washings, we would ask your child to rinse his or her mouth with water,

then gargle with 10 ml of isotonic saline for at least 30 seconds, and then spit the liquid into a container.

The biomaterials are used exclusively for the study of nasopharyngeal carcinoma and its molecular, genetic, immunological and other properties. It is very important to collect samples from as many patients as possible in order to facilitate scientific investigations, despite the rarity of this diseases.

The working group of Prof. Dr. med. Delecluse in Heidelberg is particularly interested in the role of Epstein-Barr virus in the development of nasopharyngeal cancer, whereas Prof. Dr. med. Uta Behrend's group in Munich focuses on the specific immune response against Epstein-Barr virus in patients with nasopharyngeal carcinoma. However, many issues of scientific investigation arise from the future advancement of medicine, which will allow new opportunities for research that are unimaginable today. In order to obtain biological material for such future scientific investigations, such material is collected and stored in the Biomaterial Bank of the Medical Faculty of the RWTH Aachen University (abbreviated to RWTH cBMB). The biomaterials and data are to be stored until the uselessness of the material, but no longer than 20 years, and made available for medical research.

With the transfer of biomaterials to the RWTH cBMB, they become the property of the RWTH Aachen Faculty of Medicine in accordance with the consent of the RWTH cBMB. A cooperation agreement of the Nasopharyngeal Carcinoma Study Group of the German Society for Paediatric Haematology and Oncology (GPOH) with the Medical Faculty of the RWTH Aachen ensures that the biomaterials are exclusively available to scientific cooperation partners who are interested in the research of nasopharyngeal carcinoma in its molecular, genetic, immunological and other properties and whose projects are endorsed by the Study Commission of the Nasopharyngeal Carcinoma Study Group.

Personally, you cannot expect any immediate benefit from the delivery of biomaterials for scientific research to yourself / your child. The results are for research purposes only. Feedback from the study results is therefore not provided. However, it is possible in individual cases that a researcher comes to the conclusion that an result of his research is of considerable importance for your health / health of your child. This is especially the case if there is suspicion of a previously possibly unrecognized disease that could be treated or prevented from developing, or in the case of an examination of the genetic material for the genetic predisposition of certain diseases, which is also significant for your family members and family planning. In such case, feedback may be sent to you. If you do not wish to receive any feedback, please delete the possibility of renewed contact in the "Declaration of consent for the transfer and processing of personal medical data and examination material". You can change your decision about feedback at any time by notifying us. Keep in mind that you may have to disclose health information that you receive through such feedback to other institutions (e.g. before taking out a health or life insurance policy), which may disadvantage you.

Clinical data as well as the blood samples and tissue samples are encrypted and pseudonymised prior to the analysis and storage processes. The samples, the patient's personal information and the pseudonym lists are kept strictly separate from each other. Each patient is assigned an identification number identifying the clinical data as well as the biomaterials. When issuing samples to third parties, a single pseudonym is assigned, which further increases data security. The allocation list is only accessible to an independent data trustee, who may merge the samples and clinical data with information about the donor only in exceptional cases, such as revocation of consent. Data management is provided by the Institute of Medical Informatics of RWTH Aachen University.

Scientists who wish to access the collected biomaterial will only receive the data set without identifying information such as name and address. Thus, the scientists involved in the research projects cannot trace the data back to the individual patient. Participation in the registry is confidential and is subject to data protection laws. Personal data including name, date of birth and address are kept to ensure secure patient identification in centralised assessments / consultations and for coordination between referral facilities.

Data protection in accordance with the General Data Protection Regulation (GDPR) of the European Union as of May 25, 2018

Data protection is a fundamental right set out in Article 8 of the EU Charter of Fundamental rights. The GDPR is applicable from 25th May 2018 and is designed to give individuals more control over their personal data.

With regards to your data you have the following rights:

The right to access information
You have the right to obtain information about personal data concerning you which is collected, processed or, if necessary, transmitted to third parties. You have the right to obtain a copy of your personal information (Article 15 of the GDPR).

The right to rectification
If your personal data is inaccurate, you have the right to have the data rectified, by the controller, without undue delay (Articles 16 & 19 of the GDPR).

The right to erasure
You have the right to have your data erased, if feasible (e.g. your personal data is no longer necessary in relation to the purpose for which it was collected or processed) (Articles 17 & 19 of the GDPR).

The right of restriction
You have a limited right of restriction of processing of your personal data by a data controller. Where processing of your data is restricted, it can be stored by the data controller, but most other processing actions, such as deletion, will require your permission (Article 18 & 19 of the GDPR).

The right to data portability
You are entitled to obtain your personal data from a data controller in a format that makes it easier to reuse your information in another context, and to transmit this data to another data controller of your choosing without hindrance (Article 20 of the GDPR).

The right to object to processing of personal data
You have the right to object at any time to certain types of processing of your personal data where this processing is carried out in connection with tasks in the public interest, or under official authority, or in the legitimate interests of others (Article 21 of the GDPR).

Consent and revocation option
Processing of your personal data only takes place on the legal basis of an informed consent (Article 6 of the GDPR).

You have the right to revoke your consent for processing of at any time. The withdrawal of consent shall not affect the lawfulness of processing based on consent before its withdrawal. (Article 7 (3) of the GDPR).

If you wish to exercise any of these rights, please contact your principal investigator or the data protection officer at your test centre.

The person responsible for data processing is the principal investigator of the registry:

Prof. Dr. med. Udo Kontny
Division of Paediatric Haematology, Oncology and Stem Cell Transplantation
Department of Paediatrics, University Hospital RWTH Aachen University
Pauwelsstr. 30, D-52074 Aachen
Phone: +49 241 80 88892, Fax: +49 241 80 82481
E-Mail: ukontny@ukaachen.de

The responsible data protection officer at the registry is:

Joachim Willems
Data Protection Officer of the University Hospital Aachen
University Hospital RWTH Aachen University
Pauwelsstr. 30
D-52074 Aachen, Germany
Phone: +49 241 80 89051
Fax: + 49 241 80 33 89051
E-mail: jwillems@ukaachen

The data protection officer of your study centre is:

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(Data protection officer, study centre, incl. contact data)

You have the right to lodge a complaint with the supervisory authority(ies), e.g. with:
Landesbeauftragte für Datenschutz und Informationsfreiheit Nordrhein-Westfalen
Postfach 20 04 44 40102 Düsseldorf Phone: +49 211 38424 0 Fax: +49 211 38424 10
E-mail: poststelle@ldi.nrw.de

You can reach the data protection supervisory authority responsible for your study centre at :

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(Supervising authority, contact data)

Risks and benefits:

It is important to know that there are no special risks or inconveniences for you or your child. The registry is designed to improve knowledge and treatment of nasopharyngeal carcinoma with the help of the patients. The already existing structures of the registry may benefit you or your child as well, as it makes it easier for specialists to communicate with each other and to exchange expert opinions.

Withdrawal of consent:

You can withdraw your consent at any time and without giving reasons.

Upon revocation, you can decide whether previously stored personal data may be deleted or used in anonymous form for further scientific purposes. Likewise, you can decide whether previously archived research materials should be destroyed or used in anonymous form for further scientific purposes. Anonymization means that the identification code (ID) is deleted. The ID code can be used to determine from which person the data or test samples originate.

By withdrawing consent neither you nor your child will suffer any consequence.

Questions

If you have any questions, you can write them down here: