**Subject information for participation in a medical-scientific study**

**INCbase**

*Inflammatory Neuropathy Consortium Base; an international CIDP registry*

**Introduction**

Dear Sir/Madam,

You are being asked to take part in a medical-scientific study. Participation is voluntary. In order to participate your written consent is required. You are receiving this letter because you possibly have chronic inflammatory demyelinating polyneuropathy (CIDP). Before you decide whether you want to participate in this study, you will be given an explanation what the study involves. Please take your time to read this information and ask the investigator if you have any questions. You can also ask the independent expert mentioned at the end of this letter for additional information. You can also discuss it with your partner, friends or family. Further information about participating in such a study is found in the enclosed brochure <>.

1. **General information**

This study was is being conducted by doctors and investigators in various hospitals worldwide. Various pharmaceutical companies will partly cover the costs of this study. The Medical Ethics Review Committee of the <center> has approved this study. General information about the assessment of research can be found in the brochure <>.

1. **Purpose of the study**

This study has different purposes. One of the aims is to predict the long-term effect of treatment. Another aim of this study is to collect more information about various forms of CIDP and to find out ways to measure disease activity. There will be more and different aims added in the future. The information from this study will be combined with information from other studies with comparable research questions. An overview of these study aims can be found on the INCbase website (www.INCbase.org).

1. **Background of the study**

CIDP is a rare disease. There are also a lot of differences in complaints, treatment responses and the disease course between CIDP patients. To improve care, we need to collect information of many different CIDP patients. To do this, we need international collaboration. With this study we will investigate a large number of CIDP patients throughout the world.

1. **What participation involves**

If you do participate, it will take at least 2 years. You can always decide if you do not want to participate in this study anymore. By participating your usual care will not be influenced. There is no need to use new or other medication in this study. You will remain under the usual care of your own neurologist when you participate.

**Visits and tests**

For the study, you have to visit the hospital once every 6 months. These visits will mostly be planned together with your regular visits with your neurologist. Sometimes more visits need to be done. For instance, when your disease recently has been diagnosed, is very active or when treatments are started that require frequent monitoring by your neurologist. When your treatment will be stopped or tapered, more visits will be planned to monitor possible changes in your complaints. In other cases, for example when your disease is stable, visits could be planned less often.

The study measurements in the hospital will take approximately 30 minutes. The following will take place:

* Each visit we perform a neurological examination and ask about your complaints
* Each visit we will collect blood, with a maximum of 60ml each time, to store for future measurements.
* Each visit we will ask you to complete questionnaires about your complaints and limitations, among which fatigue and pain, your quality of life, your treatment satisfaction and possible side effects. Most of the questionnaires can be filled out at home or in the waiting room.

The following tables show an overview of the visits in the first two years in different scenarios.

**Your disease is stable**

|  |  |  |  |
| --- | --- | --- | --- |
| **Hospital** | **Week 0** | **Week 24\*\*** | **Week 48\*\*** |
| Neurological examination | x | x | x |
| Grip strength | x | x | x |
| Questionnaires | x | x | x |
| Blood sampling | x | x | x |

**Treatment will be started or stopped**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Hospital** | **Week 0** | **Week 4\*** | **Week 12\*\*** | **Week 24\*\*** | **Week 36\*\*\*** | **Week 48\*\*** |
| Neurological examination | x | x | x | x | x | x |
| Grip strength | x | x | x | x | x | x |
| Questionnaires | x | x | x | x | x | x |
| Blood sampling | x | x | x | x | x | x |

\* Visits can be planned within 2 weeks before and 2 weeks after the precise date.

\*\* Visits can be planned within 4 weeks before and 4 weeks after the precise date.

\*\*\* Additional visit, if you are tapering treatment

**Home assessments**

One of the objectives in the study is to research how best to measure changes in disease activity. Some participants that will be stopping or tapering treatment in agreement with their neurologist will be asked to perform home assessments between hospital visits. In this case, you will be asked to perform home measurements of your grip strength of both hands. You will be provided with instructions and a grip strength meter to take home. In addition, you will be asked to fill in these values and questionnaires digitally. An email will be sent to you with an invite. This will take approximately 20 minutes.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Home** | **Week**  **2** | **Week**  **4** | **Week**  **6** | **Week**  **8** | **Week**  **10** | **Week**  **12** | **Week**  **16** | **Week**  **20 \*** | **Week**  **24 \*** |
| Grip strength | x | x | x | x | x | x | x | x | x |
| Questionnaires | x | x | x | x | x | x | x | x | x |

\* We can ask you to perform these additional home measurements, for example in case you are still in the process of tapering your medication.

1. **What will be expected of you**

To ensure this study runs well, it is important you adhere to the following rules:

* You will fill in the questionnaires and grip strength measurements according to plan
* You will attend the scheduled hospital visits

1. **Possible discomforts**

Blood collections may cause pain or bruising. In total, we will collect 60 ml blood each time. This amount should not cause any problems in adults. In comparison: at the blood bank, 500 mL of blood is collected at one time. Also, you will need to spend additional time for this study. If we ask you to perform home measurements, this will also cost extra time.

1. **Possible advantages and disadvantages**

It is important that you consider the possible advantages and disadvantages before you decide to participate. If you participate in this study it does not mean you will experience less burden from your disease. You will, however, contribute to more knowledge on CIDP.

Disadvantages of participation in the study may be:

* + possible discomfort of blood collections.

Participation in the study also means:

* + you will have to spend additional time.

This is described in parts 4, 5 and 6.

1. **If you do not want to participate, or would like to stop participating in the study**

You decide yourself whether you want to participate in the study. Participation is voluntary. If you do not want to take part, you will be treated as usual for your disease.

If you do participate, you can always change your mind and stop, also during the study. You do not have to explain why you are stopping. However, you should immediately inform the investigator. Data obtained thus far will be used for the study. If you wish, the already collected bodily material can be destroyed.

If there is any new information about the study which is important for you, the investigator will inform you about this. You will then be asked if you wish to continue your participation.

1. **End of the study**

Your participation in the study ends when:

* you choose to stop
* the end of the entire study has been reached
* the investigator thinks it is better for you to stop
* the <> decide to stop the study.

1. **Use and storage of your data and body material**

For this study, personal data and contact details will be collected and stored. It involves information such as your name, address, date of birth and data about your health, medical history and treatments. Bodily material that was collected during the diagnostic work-up prior to the study, for example cerebrospinal fluid, can also be stored for this study. No additional procedures, such as nerve conduction studies or lumbar punctures, will be performed within the study. The collection, use and storage of your data and your body material is required in order to answer the questions asked in this study and to be able to publish the results. For this study, blood samples may be also needed and we ask you if you agree to collecting blood samples and storing these in your hospital to be used for future analysis. You can indicate on the consent form, within the objectives of this study, if you agree with collecting and storing blood samples. if you do not agree you can still participate in this study.

This study has no commercial purpose. However, for some studies it can be relevant to cooperate with companies who do want to make a profit, like pharmaceutical companies, possibly when a new diagnostic test or treatment will be developed or because they have specific knowledge and/or equipment. Your coded (medical) information and body material will never be sold to companies. The <center> will always remain responsible and involved with the use of your (medical) data and materials. We ask your consent for the use of your data and body material. You can indicate on the consent form, within the objectives of this study, if you do not want your bodily material (and coded data) to be issued to commercial parties.

**Confidentiality of your data and body material**

To protect your privacy, your data and your body material when collected will receive a code. Your name and other information which could directly identify you, are therefore omitted. This information can only identify you with a key. The key to the code will be stored securely in the local research facility. To send you the questionnaires digitally, it is necessary that your email address is known to the local researcher. Your email address will be stored encrypted and separately from the other information and is not accessible to anyone else. The data and body material which is sent to the sponsor and any other parties involved only contain a code, and not your name or other data that can identify you. In reports or publications about the study, the data will also not be identifiable.

**Collection and storage of genetic material**

We ask your consent to store your blood as DNA which carries your genetic information. Using your DNA, we will investigate genetic factors that are associated with CIDP. Your DNA will not be used for other studies. Your DNA will be stored using a code, just like your data and other body materials. You can indicate on the consent form if you do or do not agree with this storage. If you do not consent, you can still participate in the current study.

**Access to your data for review**

Some individuals may have full access to your data at the study site. Also to the data without a code. This is mandatory in order to check whether the study is performed properly and reliably. Individuals who have access to your data for review are: <>. They will keep your data confidential. We ask your consent for this access.

**Retention period of data and body material**

Your data must be stored for <> years at the study site. Your body material will not be destroyed immediately after use. It will be stored in order to perform new assessments in the course of this study, related to this study.

**Storage and use of data and body material for other studies**

Your data and body material may still be of interest after the end of this study for other clinical research in the area of your disease. Therefore, your data and body material will be stored for <> years. You can indicate on the consent form if you do or do not agree with this storage. If you do not consent, you can still participate in the current study.

**Access to your medical information after study termination**

After termination of this study it could be possible more information from your medical chart will be required to answer the research questions of this study. Hence, we ask your consent for us to contact or consult your general practitioner, treating specialist or medical chart regarding the research questions of this study. You can indicate on the consent form if you do or do not agree. If you do not consent, you can still participate in the current study.

**Information about incidental findings**

During this study, there may be incidental findings which are relevant for you. If this is important for your health, you will be notified by your treating specialist. You can subsequently discuss with your general practitioner or specialist what needs to be done. You will also consent to this.

**Withdrawal of consent**

You can always withdraw your consent for the use of your personal data. This applies to this study and also for the storage and use for future research. The study data already collected until the time you withdraw your consent will still be used in the study. Your body material will be destroyed after withdrawal of your consent. If measurements have already been performed on this body material, then this data will still be used.

**Transfer to countries outside the European Union (EU)**

In this study your coded data and body material could also be sent to parties in countries outside the EU. This is necessary as some experts and laboratories are located outside the EU. In those countries, the EU rules to protect your personal data do not apply. We will make contractual agreements with those parties to protect your privacy in an equivalent manner. In case you do not want your body material (and/or coded information) to be issued to countries outside the EU, you can indicate this on the consent form.

**More information about your rights concerning the processing of data**

For general information about your rights concerning the processing of your personal data, please consult <>.

If you have any questions about your rights, please contact the person responsible for the processing of your personal data (please see Appendix A).

If you have any questions or complaints regarding the processing of your personal information, we recommend you to contact the study site. You can also contact the Data Protection Officer of the institution (see Appendix A) or the <>.

1. **Insurance for subjects**

If you participate in the study, you will not be at extra risk. Thus, according to the regulatory committee, the investigator, is not required to take out additional insurance.

1. **Informing general practitioner and/or treating specialist**

We will not inform your treating specialist of your participation in this study as your treatment nor diagnosis will be changed. If necessary we can contact your general practitioner or neurologists who previously treated you for your disease, for example about your medical history or medication use.

1. **No compensation for participation**

The measurements for the study cost you nothing. You will not be paid to participate in this study. In principle you will not be reimbursed for your (additional) travel expenses since the study measurements will be planned simultaneously with your regular outpatient clinic checks.

1. **Do you have any questions?**

If you have any questions, please contact the investigational team. If you would like independent advice about participation in this study, please get in touch with the independent neurologist. He/she knows a lot about the study, but has nothing to do with this study. You can discuss any complaints about the study, with the investigator or your regular doctor. If you would rather not, you can contact the complaints officer at your hospital. All data can be found in **Appendix A**: Contact information.

1. **Signing of informed consent form**

When you have had a sufficient time to think about participating, you will be asked to decide about participating in this study. If you consent, you will be asked to confirm your consent in writing on the corresponding consent form. With your written consent, you indicate you have understood the information and agree to participate in the study. Both you and the investigator will receive a signed version of this consent form.

Thank you for your attention.

1. **Appendices with this information**

A. Contact details

B. Consent form

**Appendix A: contact details for <>**

Investigator:

<>

Study physician:

<>

Independent physician:

<>

Complaints:

<>

Institutional Data Protection Officer:

<>

For more information about your rights:

<>**Appendix B: consent form subject**

INCbase

* + I have read the information letter. I was also able to ask questions. My questions have been answered sufficiently. I have had enough time to decide whether or not to participate.
  + I understand participation is voluntary. I also know I can decide not to participate or to stop participating in the study at any time. Without having to provide a reason why.
  + I give consent to information being requested from my general practitioner/specialist(s) who is treating me or has been treating me for my disease.
  + I give consent to collect and use my data, including contact details, and leftover bodily material if available to answer the research questions in this study. I know for study monitoring purposes some individuals could have access to all my data. Those individuals are listed in this information letter. I consent to this access by these persons.
  + I understand that others than the researchers listed in this letter can conduct research with my (medical) data and body materials.
  + I understand that my data from this study can be combined with information of other patients from other studies with similar research questions to this study.
  + I understand that my data and body materials can be used for research by parties outside my hospital in the European Union.
  + I give consent to my general practitioner and/or treating specialist to be informed of unexpected findings which are (or could be) of interest for my health.
  + I **□ give □ do not give** consent to collect, store and use my blood samples to answer the research questions in this study.
  + I **□ give □ do not give** consent to ask me to perform home assessments
  + I **□ give □ do not give** consent to use my blood for hereditary/genetic research associated with CIDP.
  + I **□ give □ do not give**  consent to do research with my data and material by parties in countries outside the European Union with an equal level of privacy protection and parties with whom contractual agreements have been closed to ensure an equal level of privacy protection.
  + I **□ give □ do not give**  consent to do research with my data and material by commercial parties.
  + I **□ give □ do not give**  consent for storing my personal data for future research related to CIDP.
  + I **□ give □ do not give**  consent to store my body materials after this study and to use this material at a later stage for other research, such as indicated in the information letter.
  + I **□ give □ do not give**  consent being contacted again after this study for other studies.
  + I **□ give □ do not give**  consent approaching or consulting my general practitioner, treating physician or medical file by INCbase researchers after termination of this study for additional information related to the research questions of this study.
  + I want to participate in this study.

Name of subject:

Signature: Date : \_\_ / \_\_ / \_\_

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I certify I have fully informed this subject about aforementioned study.

If information becomes known during the study which could influence subject’s consent, I will inform him/her thereof in time.

Name of investigator (or its representative):

Signature: Date: \_\_ / \_\_ / \_\_

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Additional information was provided by:

Name:

Function:

Signature: Date: \_\_ / \_\_ / \_\_

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\* Delete which is not applicable.

*The subject will receive a complete information letter, together with a signed version of the informed consent form.*