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HIV-1 Seroconverter Study

Investigation of the progression of HIV infection in patients with a known time of infection.
Analysis of epidemiological, virological, immunological and clinical parameters
with regard to the progression of the disease.

PATIENT INFORMATION SHEET

Dear patient,

We would like to invite you to voluntarily take part in the HIV-1 seroconverter study at the Robert Koch Institute. Please take your time to carefully read through this information. If you have any questions, please do not hesitate to ask. Your doctor or nurse specialist will be happy to answer any questions regarding this information sheet and the HIV-1 seroconverter study which you may have. If you have understood everything and wish to take part in the study, after taking sufficient time to think it over, you will be asked to sign the consent form.

Purpose of the study

Some people who are infected with HIV develop full blown AIDS within a few years, whilst others remain AIDS-free for 15 years or more. The reasons for these differences are currently poorly understood. Determining the reasons for this would be an important step in efforts to slow down or even stop the progression of HIV disease.

Most people with HIV do not know exactly when they became infected. Increasing awareness of HIV and AIDS means that more and more people have now taken an HIV test within the three years prior to their first positive test. Because their blood serum has changed from being HIV-antibody negative to being HIV-antibody positive (‘seroconversion’), for these people it is possible to estimate that they became infected with HIV at some time between the negative and positive HIV tests.

Although there is currently no cure for HIV, many different drugs able to inhibit replication of the virus are now available. Treatment guidelines recommend using a combination of at least three of these drugs. Such a combination of drugs is known as highly active antiretroviral therapy (HAART). The best time to start HAART can vary between patients and depends on many different factors. Your doctor will tell you whether it is advisable for you to begin HAART.

The introduction of HAART has resulted in better treatment options for patients with HIV. A major problem, however, is that, for many patients, the treatment eventually loses its effectiveness, as the virus becomes resistant to the drugs used. The result is failure of the therapy. If drug levels in the body are too low, resistant virus particles are formed during HIV replication and can be transmitted. The Robert Koch Institute study will therefore also examine how often drug-resistant viruses are transmitted in Germany and whether the frequency of transmission is increasing.

Existing studies have found that this occurs in 5-25% of all new infections in Western Europe. Patients newly infected with HIV are therefore at risk of having been infected with a strain of the virus which is

already resistant to one or more drugs. It is important to obtain this information because new infection with a resistant strain of the virus can have a permanent adverse effect on the success of treatment.

Viral resistance to currently available drugs can be determined using a blood test. The subtype of the infection can be determined from the resistance test – no other investigations are required.

It is important to understand that it is not possible to detect virus resistance in newly infected patients if the level of virus in the blood sample is below the limit of detection for the resistance test. Tests for resistance can only detect resistant viruses if they make up more than 10-25% of the total viral load.

The HIV-1 seroconverter study currently includes around 2,500 patients and is helping to improve our understanding of individual differences in the progression of the disease. Consequently, a range of different factors which may influence the progression of HIV infection are being studied. These include immune system status, the number of viral particles and the resistance characteristics of the virus. In this respect, the HIV subtype responsible for your infection is also of interest. Important co-infections, such as hepatitis B and C and syphilis are also included in the study.

There are indications that people's genes can also affect the rate of transmission of HIV, the progression of the infection and treatment and the development of certain kinds of resistance. Genetic tests carried out in the course of the study could help to clarify the effect of these genes on the progression of HIV disease and treatment. These tests are carried out using DNA samples from blood cells.

Conditions for participation

Patients taking part in the study must (i) be at least 18 years old (ii) have had an HIV test a maximum of three years prior to their positive HIV test or be newly infected (laboratory evidence of ongoing seroconversion).

Data processing

By signing the consent form, you declare that you consent to the doctor treating you recording and processing your personal data for the purpose of the above study. Personal data includes, for example, your date of birth (month and year only), sex, country of origin, health information and information on laboratory tests carried out.

The doctor treating you will pass the data collected to the Robert Koch Institute. The data passed on to the institute will not contain your name or address. Instead, the doctor treating you will assign a code number (case-related coding) to your personal data. Only the doctor treating you and his or her staff have access to the coding key which permits the study data to be identified as pertaining to you.

The Robert Koch Institute will use your encoded personal data for the purpose of administering and performing the above study. The results of the study will be published in specialist publications, but you will remain anonymous.

Data from the HIV-1 seroconverter study will be stored in a secure database at RKI. Access to this database is limited to members of the research group only.

You have the right to know about all personal data relating to you held by the doctor treating you. Your doctor is legally obliged to retain the results of your tests for ten years in his or her study documentation unless you decide that the results should be destroyed sooner.

You also have the right to have any inaccuracies in your personal data corrected.

The blood sample information taken from you as part of the above study will also be encoded and forwarded to the laboratory at the Robert Koch Institute (HIV variability and molecular epidemiology) for testing blood samples for the purpose of the above study.

The Robert Koch Institute collaborates with academic partners both in Germany and abroad on specific research issues. By linking data from several cohorts of patients, this kind of collaboration enables the

creation of a larger database for scientific analysis. This enables researchers to research phenomena which require a greater volume of data than can be provided by a single cohort.

Depending on the study, your data and blood samples may be analysed in anonymised form in laboratories or study centres in other countries. In this case, your identity will be protected just as strictly as it is when data and blood samples are forwarded and analysed in Germany.

You can withdraw your consent to the processing of data collected in the course of the above study and/or further testing of the samples taken from you at any time and request that it be deleted/destroyed.

Procedure

If you decide to take part in the study, the procedure will be as follows:

(i) Your doctor or nurse will fill in a questionnaire with you. This will take about 10-15 minutes. Data will be collected on your personal details, your state of health, how you were infected and test results.

(ii) Approximately 30 ml of blood will then be taken. In addition to the initial blood sample, around 20 ml of blood will be taken annually for annual progression investigations.

(iii) The blood samples will be tested at the RKI (resistance testing, subtype identification, tests for co-infections, testing of genetic characteristics) and components of the sample (plasma, DNA) will be kept for long-term storage, for which they will be assigned another new number, ensuring that your genetic material is doubly encoded. Genetic analysis encompasses the objectives set out above. To this end, the samples may be subjected to multiple tests.

(iv) New scientific issues relating to the progression and treatment of HIV infection which your samples may be able to help clarify may arise in the future. At present it is therefore not possible to say how long your samples will be retained.

(v) If, in the future, your blood samples could be used to investigate significantly different scientific issues, the opinion of the responsible ethics committee will be obtained beforehand.

(vi) The right to use the samples and data is held by the Robert Koch Institute. They will be stored there and may be sent to other study partners in Germany and abroad for investigation. If the samples are sent to other study partners, we will ensure that German data protection guidelines are followed. You nonetheless have the right to ask for your samples to be destroyed at any time. Where it can no longer be related to you personally, previously collected data will remain within the study after the destruction of your samples.

How will you benefit from the study?

If you have not yet received treatment, a resistance test will be carried out which will identify whether your virus is no longer able to be inhibited using one or more drugs. This knowledge can influence the choice of drugs for initial treatment, which will benefit you if you are found to have a resistant virus. The results of resistance testing and subtype identification will be provided to your doctor free of charge via the HIV-1 seroconverter study.

It is nevertheless entirely possible that participation in the study will not result in any direct benefit in terms of your treatment or your health. However, the information obtained from this study has great scientific value and may benefit you and other patients in the future.

Participation is voluntary

Participation in this project is exclusively on a voluntary basis. You have the right not to take part or to withdraw your consent at any time without giving reasons. This will not affect your treatment. The same applies should you withdraw your consent to the processing of your data and samples. Similarly, this does not preclude subsequent participation in other studies.

Confidentiality

Your participation in this study will be treated in strict confidence. To protect your private life, all information stored anonymously in the Robert Koch Institute's HIV database and used for scientific purposes will be encrypted.

Risks

Blood will be taken from you for the study. In many cases it will not be necessary to carry out additional venipuncture, as blood will need to be taken anyway. You should nonetheless be aware that venipuncture can, in very rare cases, lead to the following complications: bruising, injury to an artery and severe bleeding, injury to nerves with subsequent loss of feeling (and possibly movement), inflammation.

Insurance cover

Insurance will not be taken out on your behalf as part of this study. Any claims for liability which may arise as a result of culpable conduct by the study doctor are covered by public liability insurance.

Further information

If you would like any additional information or have any problems or questions regarding the study, you can contact your doctor or nurse specialist at any time. For more detailed questions, you are welcome to contact the study team at the Robert Koch Institute (Daniel Schmidt, Tel. 030-18754–3101, Dr. Karolin Meixenberger, Tel. 030-18754-2277).

THANK YOU VERY MUCH FOR YOUR COLLABORATION!