HepMig - Pilot-study: Hepatitis B and C care situation in Germany among people with migration background from selected countries.

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Study information

You have been asked by the study team at the HepMig Study Center if you would like to participate in a study on the hepatitis B and C care situation in Germany among people with migration background from selected countries. Please take the time to read the following information and ask any questions you might have. It is entirely up to you if you would like to participate in the study or not.

Who is undertaking the study?

The Robert Koch Institute (RKI) is the national public health institute in Germany and a central institution of the Federal Government in the field of surveillance and prevention of infectious diseases and chronic diseases.

The study will be conducted in cooperation with the local public health authority in Frankfurt. You can find the contact details in the informed consent form.

The data collection is performed in strict compliance with the EU Data Protection Regulation (DSGVO) and the Federal Data Protection Act (BDSG).

What is the aim of the study?

Hepatitis B, C and D are blood-borne and sexually transmitted diseases that can result in life-threatening chronic liver disease, such as cirrhosis or liver cancer. Hepatitis D only occurs together with hepatitis B, and the infection can cause severe acute liver damage. However, all three infections often occur initially without symptoms and thus remain undetected for a long time.

Treatment can prevent the long-term consequences of hepatitis B (and D), and hepatitis C can be cured. In addition, the risk of transmitting the infection to others can be reduced or eliminated if treated.

In some countries, such as Romania or Turkey, hepatitis B, C and D are more common than in Germany. If you were born and have lived longer in one of these countries, you may have one of these infections without knowing it.

Therefore, in the study we would like to investigate the prevalence of hepatitis B, C and D in people born in countries with increased prevalence of hepatitis B, C and D. We would also like to investigate whether certain sub-groups of the population are particularly affected. Most importantly, we would like to look into access to health care services, and treatment and care for hepatitis B, C, and D, in particular.

We are initially conducting the study only in Frankfurt and only among people born in Turkey or Romania. A large part however also consists of looking into the feasibility and acceptance of the study methods to allow developing a non-stigmatizing and well-accepted study design. We can then conduct the study in other cities in Germany, and also among people who were born in other countries.

At a later stage you will also have the opportunity to take part in a group discussion. During these discussions you will talk to the study team and also other study participants. During these interviews, our aim is to find out how your experience was with the study. For this part of the study there will be a separate information letter and consent form. You do not need to take part in the group discussions in order to participate in the study.

What will happen if I decide to take part?

Employees of a study team employed by the RKI will draw blood from your finger or vein today and send the blood to a laboratory commissioned by the RKI (MVZ Labor Krone GbR, Bad Salzuflen). There, the blood will be tested for hepatitis B, C and D. You do not have to pay anything for these tests. The laboratory results are sent back to the study team at the local public health authority and to the RKI.

We also ask you to complete a questionnaire with questions about yourself, your behavior (including sexual behavior), your risk factors for any of the infections tested, and your experience with access to health care services for hepatitis B, C, and D. This can be done either online on a tablet provided by the RKI or paper-based paper. If you wish, you can also ask one of the study team members to help you fill in the questionnaire or ask you the questions and tick your answers. All your answers will be kept strictly confidential. You will need about 20 minutes to complete the questionnaire. The questionnaire will then either be sent to the RKI online in an encrypted form or the study team members will send it to the RKI by mail in a sealed envelope.

The data collected from the questionnaire and the laboratory results are linked at the RKI.

If needed, all study materials are available in multiple languages and the study team members can translate for you. If you wish, you can also make use of language mediation by telephone. This is provided by Dolatel GmbH (Cologne). You do not have to give your name or other personal data when making use of this service. Your information will be kept strictly confidential.

Why was I selected for the study?

Any person above 18 years of age born in Romania or Turkey who has not yet participated in the study may participate.

Is participation in the study voluntary?

Yes, participation is completely voluntary. There will be no consequences for you if you chose to not take part in the study. Participation in the study will not affect your medical care. If you wish to participate in the study, please sign the informed consent form attached to this sheet.

Your consent is the legal basis for the processing of your personal data according to Article 6 paragraph 1 lit. a and Article 9 paragraph 2 lit. a in the German Data Protection Act. You can withdraw your consent at any time and without providing any reasons also in the future without any negative consequences.

What will happen to my data?

Within the scope of the study, your personal data, including data on your behavior, will be analysed. This includes, for example, information about your age and gender, your migration history and your stay in Germany, as well as your risk factors for hepatitis B, C and D infection (e.g. medical interventions, your sexual behavior and injecting drug use) and your access to hepatitis B, C and D medical care.

All information we analyse as part of this study will be kept strictly confidential.

If you participate in the study, you will receive a random, seven-digit number (ID) at the study center today. The questionnaire, lab samples and lab results will be marked with this ID (instead of your name). The ID will not be recorded at the study center.

The consent form is stored in a data protection compliant manner (usually in locked cabinets) at the local public health department in Frankfurt. The study team members and the RKI do not have access to it. The laboratory samples are sent to Labor Krone and the laboratory results from there (also marked with the ID) are further sent to the RKI. The questionnaire is sent directly to the RKI. Laboratory samples, laboratory results and the questionnaire are also stored in accordance with data protection regulations. The biological samples and questionnaire will be destroyed at the end of the study. The informed consent form will be destroyed after the end of the study.

At the RKI, the laboratory results and the data from the questionnaire are linked via the ID. The data set is stored securely on an RKI server with access only for authorized persons. The ID is removed from the data set after completion of the study, so that no further personal reference is possible. The personal data set is irrevocably deleted.

The members of the study team will not receive any information from the questionnaire you have completed. Apart from the recipients mentioned above, no other body will receive your personal data.

What are the risks and adverse health outcomes related to participation in the study?

Blood sampling can cause bruising and pain at the puncture site. In rare cases, infections or inflammations may occur at the puncture site. In very rare cases, persistent damage to nerves or blood vessels is possible.

What happens if I suffer harm as a result of participating in the study?

If you suffer any damage in connection with participation in the study, the RKI will pay for this damage directly; this applies to all risks of damage including any damage in the context of commuting accidents (i.e. also for outward and return journeys in connection with study participation). The RKI is legally obligated to do this according to the principle of self-insurance (VV No. 11 to § 34 BHO)."

Will the lab results from the study be shared with me?

The study team will receive your laboratory results with your ID by mail from Labor Krone. Today you will receive a card with your ID on it. You can use it to pick up your lab results during a medical consultation at the study center. During this consultation, if you have one of the infections, the options for treatment will also be explained to you and you will be referred to appropriate physicians if necessary. However, you are not required to pick up your test results. If you do not, the study team will also not know which lab results belong to you. All uncollected lab results will be destroyed at the end of the study.

What happens to the results of the study?

The study results will be used as a basis for deriving or adapting targeted interventions for improved hepatitis B, C and D care among people born in Romania and Turkey. In addition, they will be published in scientific journals. In the publications, only aggregated data are described and analysed, not individual data.

Will my data and/or biological samples from the study be shared with third parties?

Your data and biological samples will not be shared with third parties.

Will I incur any costs as a result of participating in the study?

Participation in the study is completely free of charge.

I am interested in participating in the study. How can I register?

Do you consent to a blood sample being taken from you and to the laboratory results being recorded and processed on electronic data carriers together with the personal data collected from the questionnaire?

If this is the case, please let the study team at the study center know that you want to participate in the study.

Thank you for your interest!