Patient Information Sheet with Informed Consent Form

Research: Molecular profiling of peripheral blood samples of pregnant patients gave birth of newborns with fetopathy on the background of maternal type 2 diabetes mellitus or gestational diabetes mellitus

Dear patient,

We invite you to take part in this study, the essence of which will be detailed by your doctor.

general information

Please read this document carefully. It contains information about the biomedical research in which you are invited to participate. You should decide whether you want to participate in this study only after you have carefully read the entire text and, if necessary, have received any additional clarification from your doctor. Participation in the study does not imply any changes in the plan of your examination or treatment. If you choose to participate in this study, you will be asked to sign a consent form. One copy with your signature and the signature of the research doctor will be handed over to you.

Purpose of the study

This study is carried out with the aim of studying new diagnostic approaches for suspected of antenatal complications during pregnancy on the background of type 2 diabetes mellitus of gestational diabetes mellitus.

Study visits and procedures

If you are in a group of patients with an established diagnosis of type 2 diabetes mellitus or gestational diabetes mellitus, you will donate a venous blood in a volume of 5 ml, urine in a volume of 15 ml, after the planned observation, which is required in accordance with the research protocol to develop new methods for the early diagnosis of this disease. If you find yourself in a group of patients with no of the certain diagnosis but with an established diagnosis requiring the corresponding surgical intervention, then venous blood in the amount of 5 ml, as well as urine in the amount of 15 ml, and surgical specimen will also be taken. The survey data and your medical records will be used to assign you to a particular group of study participants.

Participation in research

Your participation in this study is voluntary. At any stage, you can refuse to further participate in the study without giving any reason. Withdrawal from participation or early termination of participation will not affect your further treatment in any way. All data obtained by the researchers is confidential information. In all reports and publications based on the results of the study, the confidentiality of your personal data will be strictly observed in accordance with the Federal Law of the Russian Federation "On Personal Data" N 152 of July 27, 2006. At this stage, the research results are not expected to be of direct relevance to you. However, the results can improve medical knowledge and help improve the quality of diagnosis and treatment of people with the disease under study. Participation in this study is free of charge for you. There is no material reward for participating in the study.

Such studies are necessary to discover new, improved methods for the early diagnosis of urological cancers such as kidney cancer. Any research is possible only with the written consent of the patient. Please read the information below and discuss it with your doctor. Feel free to ask questions if you have any.

Please sign informed consent only if:

- if you fully understand the essence of the study and the methodology of its conduct;

- if you wish to take part in the research,

- if you understand your rights as a research participant.

Local Ethics Committee at the Perinatal Center at N.E. Baumann 29th Hospital approved this study (local protocol identifier BAU-EP2019-R035.B02 on October 15, 2019), patient information and informed consent.

Taking blood for this study is optional, but safe for you as a study participant. From a blood sample taken from you, blood plasma will be obtained, which will be transferred to the research scientists of the Research Institute of Biomedical Chemistry. V.N. Orekhovich (IBMC) to carry out this study.

When signing an informed consent to participate in the study, you should be aware that taking blood from a vein can cause some complications in the form of a hematoma. However, they can cause temporary discomfort.

Signing your informed consent implies that you understand all the information contained in this document and have had sufficient time to make a decision.

For all questions that arise during the examination, you can contact the medical researcher, junior researcher.

Contact information of the local ethical committee on ethics at the local protocol identifier BAU-EP2019-R035.B02 on October 15, 2019: 2 Hospitalnaya square, 110020 Moscow, Russia; Prof. Morozov Segey Georgievich, MD. Phone +7 (495) 609-14-00, add. 37-06.

INFORMED CONSENT FORM

Molecular profiling of peripheral blood samples of pregnant patients gave birth of newborns with fetopathy on the background of maternal type 2 diabetes mellitus or gestational diabetes mellitus

I,
_____,

"_____" _____ _____ the year of birth,

registered at _____

_____

_____

Contact phone 1 _____ contact phone 2 _____

Email _____

Additional contact person _____

Contact person's phone number _____

Contact email _____

1. I received an exhaustive explanation from a medical researcher who discussed with me the question of my participation in the study, about the nature, goals and duration of this study. The research physician conducting the study informed me of all possible health and wellness effects that may arise from participating in the study.

2. I confirm that I have completely read and understood the attached information. I was provided with complete and understandable information for the research participant. I had the opportunity to ask all my questions.

3. I have notified the research doctor of all medications I have taken in the past 3 months or are currently taking.

4. I agree to cooperate fully with the research physician and inform him immediately if I develop any unexpected or unusual symptoms.

5. I am aware that the study is experimental.

6. I understand that participation in this study is voluntary. I can withdraw my consent at any time and without giving any reason, which will in no way affect my further treatment or medical assistance.

7. I understand that authorized representatives of regulatory agencies and the ethics committee may review some sections of my medical records related to my participation in this study. By my signature, I grant them the right to access my medical records.

8. I understand that this research will collect information that will be treated as confidential. My full name and date of birth will never be given to anyone.

9. I understand that as a result of experiments carried out with my biological material, experimental data on the protein / RNA / metabolite composition will be obtained, which will be stored in scientific electronic databases in anonymized format (without specifying my identification data).

10. I will not try to limit the possible use of the research results.

11. I agree to participate in this study and to cooperate with the medical researcher and, if necessary, with authorized employees from his group and authorized employees of other organizations.

12. I agree that my attending physician or other physicians responsible for my treatment will be informed of my participation in this study.

13. I agree that my research doctor may contact my relatives or friends, the attending physician or other doctors responsible for my treatment to obtain information about my health condition if it is important for this research.

14. By signing this form, I do not lose any of my rights by law. I had the opportunity to ask questions to which I received satisfactory answers.

15. I agree to the processing and use of personal data, including last name, first name, patronymic, gender, date of birth, residence address, contact phone number, email address, details of the compulsory medical insurance policy (VHI), data on health status, diseases, cases seeking medical assistance, for medical and preventive purposes, in order to establish a

diagnosis and provide services, provided that their processing is carried out by a person who is professionally engaged in medical activities and is obliged to maintain medical secrecy.

16. I agree to provide my contact information (phone number, e-mail address) and consent to communication using the phone or e-mail for research purposes, until July 31, 2021 inclusive. The right to communicate was granted to N.V. Potoldykova, urologist, junior researcher. Institute of Urology, First Moscow State Medical University THEM. Sechenov, Ministry of Health of Russia (Sechenov University).

17. I have received a signed copy of the Patient Information and Patient Study Consent.

I, the undersigned, voluntarily agreed to participate in the study "Molecular profiling of biological samples of patients with oncological pathology associated with suspected actively proliferating neoplasms"

I, the undersigned (s), authorize the use of my blood samples obtained for the analysis of biomarkers for scientific research related to my disease / condition, as well as to use them as control samples.

FULL NAME. (*filled in by the patient's hand*)
_____ _____ _____

Patient's signature _____ _____ _____ Date (*filled in by the patient's hand*)
_____ __ _____

Signature of legal representative _____ ____ ___ Date (*hand of legal representative*)
_____

Name of the attending physician-researcher N.V. Potoldykova

Signature _____ __ _____ Date
_____ _____ _____