Multicenter observational program AIVARIX

Protocol N° IC4-05682-071-RUS

NCT05764317

A study to evaluate a accuracy of the AIVARIX AI-based application in detecting signs C 1-2 classes of CVD in outpatients seeking consultancy of phlebologists in the Russian Federation.

24\10\2022

AIVARIX

A PROSPECTIVE OBSERVATIONAL (NON-INTERVENTIONAL) MULTICENTRE STUDY TO EVALUATE A ACCURACY OF THE AIVARIX AI-BASED APPLICATION IN DETECTING CEAP C1-C2 CLASSES OF CVD IN OUTPATIENTS SEEKING CONSULTANCY OF PHLEBOLOGISTS IN THE RUSSIAN FEDERATION

Dear patient,

you are being invited to take part in this observational study because you have come to a phlebologist with complaints that are characteristic of chronic venous disease (CVD). It is important that you have enough time before making a decision to participate in this study to discuss all relevant questions with your physician to be able to understand what a purpose of the program is and what its goals are. Please spare time you need to carefully read information provided here below and in case there are uncertainties that require clarification or if you need more details regarding your participation in the study please do not hesitate to address your questions to the physician responsible for the study. Please note that this observational study will be carried out in 20 clinical sites in Russia and will include about 414 patients for observation.

What is the purpose of this study?

The purpose of this study is to evaluate a accuracy of the AIVARIX AI-based application in detecting symptoms early stages of CVD in outpatients seeking consultancy of a phlebologist. This app is designed to raise awareness among patients about the need to see a doctor promptly when signs of early stages of chronic venous disease appear.

Do you have to take part?

Your participation in this study is entirely voluntary. It is your choice to take part in this study or not.

If you decide to take part in the study you are still free to withdraw at any time without giving any reason. Your research doctor may ask you the reason for your withdrawal to which you are free to answer or not. Your decision to withdraw will not affect the standard of care you receive and you will continue to receive the same level and quality of medical treatment as before. Any information collected on you up to the point of withdrawal can be used for scientific analysis purpose.

What does this study involve?

This study includes one visit. During this visit, the doctor will collect the following information about you: age and gender. The doctor will ask you about complaints and symptoms of the disease. Then the doctor will conduct an examination. If necessary, the doctor will offer you to undergo an ultrasound examination of the veins of the lower extremities. After making a diagnosis, the doctor will take one photograph of the area of the skin of the lower extremity where the changes are located (reticular veins, varicose veins, etc.). If there are no skin changes, a photograph of the unaltered area of the skin will be taken. Your participation in this study will not include any additional clinical examinations, tests or treatments other than the usual recommended set of diagnostic procedures.

The doctor may ask you about medications you have taken for venous diseases and any possible side effects you may have experienced in the past.

This concludes your participation in the study.

Then the doctor will prescribe you the treatment and continue to follow-up you as part of the routine clinical practice.

What are the possible risks and benefits of taking part in this study?

This study involves only the collection of information about your health status in the routine clinical practice settings. Therefore, participation in this study will not affect the care you receive and, therefore, there are no risks associated with participating in this study. This study is observational in its nature, and there is no direct benefit for you from participation in it. However, information collected during this study may help evaluate an accuracy of the AIVARIX AI-based application in detecting signs early stages of chronic venous disease, which in turn will increase awareness of patients about the potential presence of venous diseases signs of the lower extremities and the need for consulting with a medical specialist.

Who is sponsoring this study?

The study is sponsored by a pharmaceutical company Servier JSC (AO Servier).

DATA PROTECTION

What personal data are we talking about?

Your personal data are data relating to you that may be provided directly by yourself to your research doctor and/or may be collected indirectly (from your medical records).

The categories of personal data collected are as follows: demographic data (gender, age).

As to identification data, your first name and last name will be known only by your research doctor and, if necessary, by the staff/authorised persons from Servier company, who are in charge of controlling the quality of the study. For other people involved in the study (including the sponsor), you will be deidentified by a unique participant number (coded data) without mentioning your name. Your research doctor will securely keep the correspondence table between your name and your participant number (at the research site).

Why do we process your personal data?

Use of your data for the purpose of the study and/or in connection with your disease:

- Data obtained during the study will be used for the scientific purpose of the study only. They may be used after the end of the study in connection with your disease.
- The use of your data is mandatory: it is not possible to participate in the study without having your personal data processed. Your personal data will be processed only in an anonymized form, according to the identification number assigned to you.

Use of data for other purposes:

Your coded data may be used after the end of the study to advance science, medicine and public health. In these cases, the data may be shared with private or public third-parties (such as academics, researchers, partners) with appropriate safeguards. In no case neither your name nor any direct identifier obtained during the study are subject to disclosure or transfer to third parties. Such use may have to be approved by Ethics Committees and Competent Authorities beforehand.

CONTACTS	
Data Protection Contact *to ask questions and help you exercise your rights*	***Your Research Doctor*** *Include address and phone number*
Local / National Data Protection Authority *to lodge a complaint regarding the protection of your data*	Federal Service for Supervision of Communications, Information Technology, and Mass Media (Roskomnadzor) 7, bldg. 2 Kitaigorodskiy proezd, Moscow, 109992

CONSENT FORM

By signing this Consent form, I confirm that:

- I have been given a full explanation of the nature, purpose and duration of the study.
- I was able to ask questions regarding all aspects of the study.
- I agree to voluntarily take part in this study.
- I have noted that I am free to withdraw from the study at any time if I so desire.
- I have been informed that my personal data will be used for research purposes and/or in connection with my disease and may be used for other purposes as specified in the *Participant Information*.

Participant

First name and last name	*Date*	*Signature*

Investigator

First name and last name	*Date*	*Signature*

Witness(es) *(if applicable)*

First name and last name	*Date*	*Signature*

Give one signed original of this Patient Information and Consent Form to the participant and keep the other signed original in the study file.