Multicenter observational program VAP-PRO-C6

Protocol N° IC4-05682-066-RUS

NCT04757766

Effectiveness and tolerability of venoactive drugs in combination therapy and their effect on the overall treatment outcomes in patients with chronic venous diseases of CEAP classes C6 in real clinical practice.

23\12\2020

PATIENT INFORMATION AND CONSENT FORM
FOR PARTICIPATION IN THE PROGRAM

IC4-05682-066-RUS **Patient's ID ______**

Doctor's ID ______

You are invited to participate in an observational program. It is important that before you make a decision, you understand why this observational program is carried out and what it will be consist of. Please take enough time to read carefully the information below and discuss it, if necessary, with your doctor. If something is unclear or you want to get more information, please, ask questions to the doctor responsible for the study.

Please don't rush in making decision about whether or not to participate in the program. Please note that your treatment will not depend on your participation in the program.

If you decide to participate in the study, you will be asked to complete, sign and date this Patient Information and Consent Form for Participation in the Program. You will also be asked to keep this form, since it provides useful information about details of the program and contact telephone numbers of the doctor.

It is important that you understand that your treatment will not change anyway in relation to your participation in this observational program. Your doctor will be giving you the drugs and performing the diagnostic tests, which are usually prescribed for your disease.

This study is organized and financed by JSC Servier (a sponsor).

Aim of the program

Evaluation of the effectiveness and tolerability of venoactive drugs in combination therapy and their effect on the overall treatment outcomes in patients with chronic venous diseases of CEAP classes C6 in real clinical practice.

Participation in the program

The study is planned to enrol approximately 400 patients with chronic venous disease (CVD). You was invited to participate in this study because you had been diagnosed with symptoms and signs of CVD.

You must make an independent decision about whether or not to participate in this observational program. If you agree to participate in the program, you retain the right to refuse your participation in it at any time. In this case, the doctor responsible for the program may ask you about your reasons for refusal. Your

decision to withdraw from the program will not affect the quality of your medical care.

Procedures in the program

During this observational program, the data on your routine treatment will be recorded for 3 months. If you stop treatment before the end of the program, the doctor may still continue anyway to record data on the safety of use of the conservative treatment as long as he/she considers it necessary. In any case, the doctor will continue to follow-up you in accordance with routine medical practice.

During the program, the doctor will be collecting certain information about you. It will include personal data (e.g., gender, age, body mass and height) and the data about your health state (e.g., history of your disease and its treatment, and comorbidities). As part of the program, you will be asked to complete a patient questionnaire. The CIVIQ-14 Patient Questionnaire was created specifically to assess the quality of life of patients with chronic venous diseases. The purpose of this questionnaire is to determine the dynamics of the patient's quality of life before treatment and at the end of observation. Filling out the questionnaire will take no more than 5-7 minutes.

In order to have possibilities to contact you, the doctor will ask you to tell him/her your contact information.

Responsibilities and duties of the patient

Your daily activity will not be changed and restricted in any way in relation to participation in this observational program. You will continue to take medicines prescribed to you by your doctor, to visit a doctor and to undergo examination as required in the routine treatment of your disease.

For the purposes of this observational program, you will need to inform your doctor all the information about symptoms occurring during the participation in this observational program. You should also inform your doctor about all the new medications that you will be taking during the program.

Potential benefits and risks associated with participation in the program

Since your participation in this observational program will not affect your treatment and assessment, there are no additional benefits for you, as well as any risk or inconveniences directly related to participation in this program.

However, if you agree to participate, you will contribute to collecting the additional information about the effectiveness and safety of conservative therapy for CVD and, therefore, to the treatment of this disease.

Confidentiality and anonymity of the data

If you agree to participate in the program, all of your personal data received during this observational program will be kept confidential. They will be used for the study purposes only.

Any information about you that will be transferred outside the medical institution where the program is carried out will be anonymous. Any transfer of such data will be in accordance with the rules for the protection of personal data during their processing and transmission.

Results of the program

Data and the results of this observational program may be published in medical journals or used in scientific reports, but your name will not be mentioned in any circumstances.

Contacts for answers to the questions

If during in the course of this observational program you will have any question about the nature of this program or the medications used, please contact your treating physician by phone: _____.

Thank you for reading this information.

INFORMED CONSENT FORM

I, the undersigned (full name)

_____,

residing at the address: _____

_____

give voluntary consent to participate in the following observational program: **VAP-PRO-C6**

Doctor, who discussed with me the question of my participation in this observational study, gave me thorough explanations as to the nature, purpose and duration of the program. I had an opportunity to ask him/her questions about all aspects of this observational program, and I was told the name of the person to whom I can contact for any issues arising in the course of the observational program.

After due consideration, I agree to cooperate with doctor, who is responsible for the study: ……..
(full name of the doctor), and, if necessary, with all authorized persons. I will promptly notify them of any changes to my well-being, health and treatment.

I understand that I can refuse to participate in this observational program at any time if I want it, and it does not affect the quality of care provided to me.

All information about me will be kept confidential, and my name will never be disclosed. I agree that my medical records and other personal information obtained in the course of this observational program may be inspected by representatives of the sponsor and the persons working on its behalf, as well as representatives of the Ethics Committee and public health authorities. I agree not to interfere with any use of the results of this program.

I received one signed original of this Patient information and Consent Form for the Participation in the Program.

Patient

Date: «_____» _____ 20___.

Signature: _____

Doctor responsible for obtaining the consent

Full name: _____

Date: «_____» _____ 20___.