Multicenter observational program

VAP-PRO-C3

Protocol n° IC4-05682-055-RUS

NCT03722836

Evaluation of the efficacy and safety of vasoactive drugs as a part of combination treatment, and its influence on the general outcomes of treatment of patients with chronic venous edema (CEAP class C3) in real clinical practice.

01/09/2018

PATIENT INFORMATION AND INFORMED CONSENT FORM FOR PARTICIPATION IN THE STUDY

You are invited to participate in the observational study. It is important that before deciding, you understand why this observational program is being conducted and what it will include. Please spend enough time to read carefully the information below and discuss it, if necessary, with your doctor. If you do not understand something or you want to get additional information, ask questions to the doctor responsible for the study.

Please take enough time when making your decision on whether to participate in the study or not. Please note that your participation in the study will not affect your current treatment.

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

It is important that you understand that your treatment will not be changed in any way due to your participation in this observational study. Your doctor will prescribe to you those medications and investigations that are usually prescribed for your disease.

This program is organized and funded (i.e. sponsored) by Servier JSC.

Aim of the study:

Evaluation of the efficacy and safety of vasoactive drugs as a part of combination treatment, and its influence on the general outcomes of treatment of patients with chronic venous edema (CEAP class C3) in real clinical practice. Protocol № IC4-05682-055-RUS

Information about the drug:

The efficacy and safety of Detralex in patients with symptoms of chronic venous insufficiency (CVI) was evaluated in more than 5,000 patients participating in clinical trials. These studies demonstrated that Detralex (micronized purified flavonoid fraction) significantly improves the status of patients with signs and symptoms of chronic venous diseases.

Currently, there are other medicines to treat CVD symptoms. Your doctor will prescribe the treatment, which is the best for you. Your participation in this observational study will not affect your prescriptions made by the doctor.

Participation in the study:

A total of about 1350 patients with CVD is planned to participate in the study. You were invited to participate in this program, because you were diagnosed with symptoms and signs of CVD, and your doctor considers it necessary to prescribe you Detralex for the treatment of this disease.

You must decide on your own whether you will participate in this observational study or not. If you agree to participate in the study, you reserve the right to refuse to participate in the study at any time. In this case, the doctor responsible for the study may ask you about the reasons for your

refusal. Your decision to stop participating in the study will not affect the quality of your medical care.

Procedures in the study:

During this observational study, the data on your routine treatment will be recorded for 3 months. If you stop treatment before the end of this study, the doctor can still continue to record data on the safety of conservative treatment until he/she considers it necessary. In either case, the doctor will continue to observe you in accordance with routine medical practice.

During the study, the doctor will collect certain information about you. It will include personal data (for example, your gender, age, height and body mass) and your health status (for example, the history of your disease, current treatment, and concomitant diseases). In order to contact you, the doctor will ask you to tell him/her your contact details.

Responsibility and duties of the patient:

Your daily activity will not be changed and will not be limited in any way due to participation in this observational study. You will continue to take those medications that have been prescribed by your doctor, to visit a doctor and to undergo an examination as necessary in the routine treatment of your disease.

For the purposes of this observational study, you will need to provide your doctor with all the information about all the symptoms and complaints arising during the study. You will also need to inform the doctor about all the new medicines that you are going to take during the study.

Potential benefits and risks associated with participation in the study:

Since your participation in this observational study will not affect your treatment and examination, there is no additional benefit for you, as well as the risk or any inconvenience directly associated with participation in this study.

However, if you agree to participate in the study, you will contribute to obtaining additional information on the efficacy and safety of conservative treatment of this disease and, accordingly, to the treatment of this disease.

Confidentiality and anonymity of data:

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

Any information about you that will be passed outside the medical facility, where the study is conducted, will be anonymous. Any transmission of such data will comply with the rules for protection of personal data when processing and transmitting them.

Results of the study:

The data and results of this observational study can be published in medical journals or used in scientific reports; however, your name will never be mentioned under any circumstances.

Contacts for answers to questions:

If during this observational program you have any questions about the nature of the study or medicines used during the study, please contact your doctor

_____

by phone: _____.

Thank you for reading this information.

PARTICIPANT DECLARATION

I, the undersigned, (please indicate first name and surname)

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residing at the address (please indicate address):

. . . . . .

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hereby declare that:

I voluntarily agree to participate in the VAP-PRO-C3 program.

I was given a full explanation about informed consent, in relation to the nature, purpose and duration of the program. I had an opportunity to ask doctor any questions about all aspects of the program.

After due consideration, I agree to cooperate with a doctor-investigator, professor / doctor . . . ., and with all designated persons from his/her team. I will inform them immediately of any identified deviation.

I noted that I am free to leave the program at any time if I desire that, and my decision will not affect the standard of care that I receive. I noted that doctor-investigator will respect my right to access my personal data and correct them, if necessary.

My identity will never be divulged, and any information collected will remain confidential. I agree that my medical records and other personal data received during the program can be examined by the sponsor's representatives and by people working on behalf of the sponsor, members of the ethics committee, and representatives of the competent authorities. I agree that I will not limit the use of the results of the program in those areas in which they can be applied.

Participant	Person, responsible for obtaining the informed consent
Date: . . . . . Signature:	First name and surname: . . . . . Date: . . . . . Signature: