The Russian Multicenter Observational Program

Obtaining of data on the impact of different treatment modalities on the quality of life of the patients with acute and chronic hemorrhoid disease (EQUALISER)

NCT03743311

Protocol № IC4 -05682-058-RUS

Data of report: 1/03/2019

PATIENT INFORMATION AND INFORMED CONSENT FORM FOR PARTICIPATION IN THE PROGRAM

You are invited to participate in the observational program. 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 program or not. Please note that your participation in the program will not affect your current treatment.

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

This program is aimed at obtaining data on the effect of method and type of therapy on the quality of life of patients suffering from acute or chronic hemorrhoids.

Participation in the study:

A total of about 900 patients suffering from acute or chronic hemorrhoids are planned to participate in the program. You were invited to participate in this program, because you were diagnosed with symptoms and signs of hemorrhoids.

You must decide on your own whether you will participate in this observational program or not. If you agree to participate in the program, you reserve the right to refuse to participate in it at any time. In this case, the doctor responsible for the program may ask you about the reasons for your refusal. Your decision to stop participating in the program will not affect the quality of your medical care.

Procedures in the study:

During this observational program, the data on your routine treatment will be recorded for 3 months. If you stop treatment before the end of this program, 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 program, the doctor will collect certain information about you. It will include personal data (for example, your gender, age, height and weight) and your health status (for example, the history of your disease, current treatment, and concomitant diseases). Doctor will also ask you to complete the Quality of Life questionnaire SF36. In order to contact you, the doctor will ask you to tell him/her your contact details.

Responsibility and duties of a patient:

Your daily activity will not be changed and will not be limited in any way due to participation in this observational program. 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 program, you will need to inform your doctor of all the information about all the symptoms and complaints arising during the observational program. You will also need to inform the doctor about all the new medicines that you will take 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 examination, there is no additional benefit for you, as well as the risk or any inconvenience directly associated with participation in this program.

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

Confidentiality and anonymity of data:

If you agree to participate in the program, all your personal data obtained during this observational program will be kept confidential. They will be used only for the purpose of the program and can be submitted to public health authorities in an anonymous form.

Any information about you that will be passed outside the medical facility, where the program 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 program:

The data and results of this observational program can be published in medical journals or used in scientific reports, but your name will never be disclosed under any circumstances.

Contacts for answers to questions:

If during this observational program you will have any questions about the nature of the program or medicines used during the program, please contact your doctor _____
_____
by phone: _____.

Thank you for reading this information.

INFORMED CONSENT FORM

I, the undersigned,_____
(Surname, First name, and Patronymic name)

residing at the address _____,

provide my voluntary consent to participate in the following observational program:

Obtaining of data on the impact of different treatment modalities on the quality of life of patients with acute and chronic hemorrhoid disease

The doctor, who discussed with me the matter of my participation in this observational program, gave me exhaustive explanations about the nature, purposes and duration of the program. I had an opportunity to ask him/her questions about all the aspects of this observational program, and I was told the name of the person to whom I can apply for any questions arising during the observational program.

After due consideration, I agree to cooperate with the doctor responsible for the observational program and, if necessary, with all persons authorized by him. I will immediately inform them of any changes in my health state.

I understand that I can terminate my participation in the observational program at any time, and this will not affect my further treatment.

All information about me will be kept confidential, and my name will never be disclosed. I agree that my medical records and other personal data obtained during this observational program can be checked by representatives of the sponsor and by persons working on behalf of it, as well as representatives of the ethics committee and public health authorities. I agree not to preclude any use of the results of this program.

I received one signed original of this Patient information form and Informed Consent Form for participation in the program..

Patient

Date: «_____» _____ 201__

Signature: _____

Doctor responsible for obtaining the consent

Surname, First name, and Patronymic name: _____

Date: «_____» _____ 201__