Multicenter observational program HDQ

Protocol N° IC4-05682-063-RUS

NCT04943666

The Russian multicenter observational study «Evaluation of the HDQ for the diagnosis of hemorrhoidal disease».

28/06/2021

PATIENT INFORMATION AND CONSENT FORM FOR PARTICIPATION IN THE PROGRAM

«The assessment of the diagnostic accuracy of the questionnaire HDQ* for the diagnosis of hemorrhoidal disease»

IC4-05682-063-RUS **Patient's ID** ______\

Doctor's ID ______\

Clinical center name……

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 in duplicate, one of which will be issued to you and another will be kept by the doctor. 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 these symptoms.

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

Aim of the program is:

• To identify the sensitivity and specificity of the patient questionnaire HDQ when used as a screening tool for diagnosis of hemorrhoids

• To determine the prevalence of hemorrhoids among patients in the present study

• To evaluate the frequency of occurrence of clinical symptoms of hemorrhoids in the present study

Participation in the program:

The study is planned to enroll approximately 415 patients suffering from a coloproctological disease. You were invited to participate in this study because you had been diagnosed with symptoms and signs of hemorrhoids.

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 of the program:

This observation program includes only one visit to the doctor. The doctor will ask you to complete the HDQ questionnaire, which will take no more than 10 minutes. Further, the doctor will collect certain information about you. It will include personal data (e.g., gender, age, body mass, height) and data about your health state (e.g., symptoms

and signs of disease). In order to have possibilities to contact you, the doctor will ask you to tell him/her your contact information.

*Hemorrhoid disease questionnaire

Regardless of your decision to participate or not to participate in this study, the doctor will continue to observe you in accordance with standard / daily medical practice.

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.

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 in the program, you will contribute to creating a specific Patient questionnaire for a widespread clinical use. It is assumed that the use of the questionnaire will increase patient awareness of the disease and facilitate the prior consultation with a specialist for medical treatment.

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 and may be submitted to the public health authorities solely in the depersonalized/anonymous form.

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 any question about the aim, procedures of this program, or the medications used in this program, will arise during the course of this observational program, please contact your treating physician by phone: _____.

Thank you for reading this information.

CONSENT FORM

I, the undersigned (surname, first and patronymic name)

_____ ,

give voluntary consent to participate in the following observational program

«The assessment of the diagnostic accuracy of the questionnaire HDQ for the diagnosis of hemorrhoidal disease»

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, and, if necessary, with all authorized persons.

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 received by 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 scientific use of the results of this program.

I signed the Patient information and Consent Form for the Participation in the Program in duplicate, one of which will be issued to me and another will be kept by the doctor.

Patient

Date: «_____» _____ 2021__.

Signature: _____

Doctor responsible for obtaining consent

Surname, first and patronymic name: _____

Date: «_____» _____ 2021__.