Informed Consent Form

Multicenter, observational, non-controlled, open-label program

TRICOLOR

The use of TRIple fixed-dose COmbination in the treatment of arteriaL hypertension: opportunity for effective BP control with cOmbined antihypertensive theRapy

Protocol № IC4-06593-057-RUS

NCT03722524

25/06/2018

You are invited to participate in the observation program TRICOLOR. This means that you have been diagnosed with arterial hypertension, and your doctor has decided to prescribe you a fixed combination of amlodipine / indapamide / perindopril arginine, an antihypertensive drug, before your inclusion in this observational program.

It is important that before deciding, you understand why this observational program is conducted, and what it will consist of. 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 the doctor responsible for the program.

Please take your time for making a decision on whether you will or will not participate in the program. 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 the *Patient information and informed consent form* for participation in the program. You will also be asked to keep this form, as it contains useful information about the details of the study and the contact numbers of the doctor.

This program is observational, which means that participation in it does not affect in any way the decision of the doctor on how you are treated or examined. Your doctor will prescribe you those medications and investigational methods that are usually prescribed for your condition.

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

Aim of the program:

The program is aimed to assess the efficacy of blood pressure (BP) control and tolerability of treatment with a triple fixed-dose combination of amlodipine / indapamide / perindopril arginine in the real clinical practice in patients with arterial hypertension (HT), to whom the doctor decided to prescribe the drug prior to inclusion in the program.

Information about the drug:

A triple fixed-dose combination of amlodipine / indapamide / perindopril arginine is indicated for the treatment of arterial hypertension. Amlodipine, indapamide and perindopril arginine have been studied in numerous studies involving tens of thousands of patients. Currently, there are other medicines for treating arterial hypertension. Your doctor will prescribe the best treatment for you. Your participation in this observational study will not affect the prescriptions made to you by the doctor.

Participation in the program:

It is planned that approximately 1,650 patients with arterial hypertension will participate in this program. 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 the program at any time. In this case, the doctor responsible for the program can 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 of the program:

During this observational program, the data about your routine treatment will be recorded within 3 months. If you stop treatment before the end of this study, the doctor can still continue to record the data relating to the safety of treatment until he/she considers it necessary. In any 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, gender, age, body weight and height) and your health status (for example, the history of your disease, current treatment, and concomitant diseases). In order to contact you, the doctor should ask you to provide him/her with your contact information.

During the visit, the doctor will measure blood pressure (BP) and heart rate (HR) and ask you to fill out a questionnaire regarding the quality of life and your compliance with treatment.

Responsibilities and duties of the patient:

Your daily activity will not change 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, visit a doctor and undergo examinations as necessary during the routine treatment of your disease.

For the purposes of this observational study, you will need to tell your doctor about the symptoms that occurred during participating in this observational study. You will also need to inform the doctor about all the new medicines that you will take during the study.

Potential benefits and risks associated with participation in the program:

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

However, if you agree to participate in the program, you will contribute to obtaining additional information about the efficacy and safety of therapy for arterial hypertension.

Confidentiality and anonymity of data:

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

Any information about you that will be transferred outside the medical facility where the research is conducted will be anonymous. Any transfer of such data will be done in accordance with the rules for the protection of personal data when processing and transferring 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.

The contact for answers to questions:

If during this observational study you will have any questions about the nature of the study or the drugs used in this study, please contact the treating physician by phone: _____ .

Thank you for reading this information.

PATIENT INFORMATION AND INFORMED CONSENT FORM

I, (Surname, First name, Patronymic)

_____

confirm my consent to participate in the

MULTICENTER, OBSERVATIONAL, OPEN-LABEL PROGRAM “TRICOLOR”.

I received explanations about the purpose of the program and the effect of antihypertensive drugs.

I was informed that I will need to visit the hospital _____ at least 4 times during 3 months and attend the doctor _____, as well as to perform the necessary examinations.

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

I was informed about the need to comply with the prescribed diet and exercises, as well as the dosage regimen of the drug.

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

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.

Patient’s signature _____ Date _____ | ____ | _____

Doctor (Surname, First name, Patronymic) _____

Doctor’s signature _____ Date _____ | ____ | _____

This copy must be given to the patient

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Patient’s signature _____ Date _____ | ____ | _____

Doctor (Surname, First name, Patronymic) _____

Doctor’s signature _____ Date _____ | ____ | _____

This copy must be kept by the doctor