STYLE

Assessment of the efficacy and tolerability of the fixed-dose combination of bisoprolol/perindopril in patients with arterial hypertension and stable CAD in daily clinical practice

IC4-05150-056-RUS

NCT03730116

Data: 08/08/2018

PATIENT INFORMED CONSENT FORM

You are invited to participate in the observational study SLYLE. It means that you have revealed arterial hypertension and stable coronary artery disease (CAD) and your doctor decides to prescribe FDC with beta-blocker bisoprolol and ACE inhibitor perindopril before inclusion in this 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 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:

To assess the efficacy, tolerability and adherence of bisoprolol/perindopril FDC in patients with HT and stable CAD in real clinical practice, to which the doctor decided to prescribe it before inclusion in the program.

Information about the drug:

The fixed-dose combination of bisoprolol and perindopril is indicated for treatment of patients with arterial hypertension and/or stable CAD, and/or stable chronic heart failure with reduced systolic function of the left ventricle in adult patients for cause of bisoprolol and perindopril therapy in appropriate dose. Perindopril and bisoprolol were studied in huge number of studies and thousands of patients were involved. Nowadays there are the other drugs to treat the symptoms of arterial hypertension and stable CAD. Your doctor will prescribe the best treatment for you. Your treatment will not be changed in any way due to your participation in this observational study.

Participation in the study:

A total of about 1920 patients with arterial hypertension and stable CAD is planned to participate in the study.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.

During the at the regular visit, the doctor will measure your blood pressure (BP) and heart rate (HR) and ask you to fill out a questionnaire regarding the quality of life and your adherence to therapy. He will also ask you to keep a diary with records of blood pressure, heart rate, the number of angina attacks (chest pains) and the number of taking of short-acting nitroglycerin in the event of such attacks during each week.

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, you will also keep a diary with records of blood pressure, heart rate, the number of angina attacks and the number of taking of short-acting nitroglycerin in the event of such attacks during each week.

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 arterial hypertension and stable CAD.

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

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by phone: _____.

Thank you for reading this information.