PRIDE

Assessment of the efficacy, adherence and tolerability of the single pill combination bisoprolol/PerindopRil In patients with previous myocardial infraction with arterial hypertension in the Daily clinical practicE

Protocol №: №IC4-05150-065-RUS

NCT04656847

10 March 2020

Patient Information

Dear

_____,

Your doctor takes part in an observational non-interventional program aimed at evaluating the efficacy of and therapeutic response to Prestilol® in its everyday practical use for the treatment of hypertension in post-myocardial infarction patients.

This study will not change the quality of care provided to you and will not affect the doctor's decision regarding treatment. You may be invited to take part in the study only if your doctor decides that you need to take Prestilol® to eliminate symptoms of arterial hypertension and coronary artery disease (CAD). If you participate in this observational program, you will be asked to visit your doctor an additional 2 times (after 1 and 3 months from the start of the study) in order to analyze the treatment response. During the study, each visit doctor will ask you to complete one adherence questionnaire.

Your clinical information will be transmitted completely anonymously by your doctor to a responsible professional subcontractor for statistical analysis. Your surname and first name, as well as any other information that may be directly or indirectly used for your identification, will not be disclosed.

You are absolutely free to accept or reject, without the need for an explanation, the proposal of using your clinical information in this study. Your decision will not affect the treatment you receive from your doctor in any case.

If you need for additional information, please do not hesitate to contact your doctor.

Information about the drug

A fixed-dose combination of perindopril and bisoprolol is indicated for the treatment of arterial hypertension and/or stable coronary artery disease and/or stable chronic heart failure with reduced left ventricular systolic function in adult patients, who have indications for the treatment with perindopril and bisoprolol in the appropriate doses. Perindopril and bisoprolol have been studied in numerous studies involving tens of thousands of patients. Other drugs are currently available to treat symptoms of hypertension and CAD. Your doctor will prescribe the best treatment for you. Your participation in this observational study will not affect the prescriptions your doctor gave to you.

Thank you for your collaboration!

Informed Consent Form

ATTENTION: This statement must be signed in duplicate, and one of originals must be kept in the patient's clinical documentation file.

PRIDE: Assessment of the efficacy, adherence and tolerability of the fixed-dose combination Prestilol® (bisoprolol/perindopril) in post-myocardial infarction patients with arterial hypertension in the daily clinical practice.

STATEMENT OF PATIENT CONSENT

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

_____

resident at (specify address)

_____,

voluntarily agree to participate in the PRIDE study.

I was given a full explanation from _____, who led the discussion on informed consent regarding the nature, purpose and duration of the study. I had an opportunity to ask him/her questions regarding any aspect of the study. I was informed of the name of the contact person with whom I can contact if I have any questions during the study.

Having thought it over properly, I agree to cooperate with the investigator, professor/doctor _____, and all the assigned persons from his/her team. I will immediately inform them of any observed deviations.

I noticed that I am free to stop participating in the study at any time when I wish, and that my decision will in no way affect the standards of treatment that I receive. I noted that the invetigator will apply his access rights and corrections, if necessary, to correct any of my personal data.

My personal data will never be disclosed, and any information collected will remain confidential. I agree that my medical documents and other personal data obtained during the study can be reviewed by representatives of the sponsor and people working on behalf of the sponsor, members of the Ethics Committee, as well as representatives of the competent authorities. I agree not to create obstacles to the use of data in the field in which the results of the study can be applied.

Patient	Treating doctor
Date: _____ Signature: _____	Surname and first name: _____ Date: _____ Signature: _____

Informed Consent Form (DOCTOR's copy)

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