Multicenter observational program TARGET

Protocol N° IC4-05153-070-RUS

NCT05764317

DescripTion of the effectiveness, safety, tolerability and adherence to Amlodipine/atoRvastatin/perindopril sinGle pill combination trEatmenT in patients with arterial hypertension and dyslipidemia in the daily clinical practice.

11\08\2022

TARGET

DescripTion of the effectiveness, safety, tolerability and adherence to AmlodipineRvastatin/perindopril sinGle pill combination trEatmenT in patients with arterial hypertension and dyslipidemia in the daily clinical practice (TARGET)

AN AMBISPECTIVE, OBSERVATIONAL (NON-INTERVENTIONAL), MULTICENTER STUDY TO DESCRIBE ANTIHYPERTENSIVE AND HYPOLIPIDEMIC EFFECTIVENESS OF A TRIPLE SINGLE PILL COMBINATION OF AMLODIPINE, ATORVASTATIN AND PERINDOPRIL IN PATIENTS WITH ARTERIAL HYPERTENSION (HTN) AND DYSLIPIDEMIA IN THE DAILY CLINICAL PRACTICE.

Dear patient,

you are being invited to take part in this observational study because you are suffering from arterial hypertension and dyslipidemia. It is important that you have enough time before making a decision to participate in this study to discuss all relevant questions with your physician to be able to understand what a purpose of the program is and what its goals are. Please spare time you need to carefully read information provided here below and in case there are uncertainties that require clarification or if you need more details regarding your participation in the study please do not hesitate to address your questions to the physician responsible for the study.

Please note that this observational study will encompass about 20 clinical sites in Russia and about 400 patients will be included for observation.

What is the purpose of this study?

The purpose of this study is to describe antihypertensive and hypolipidemic effectiveness of a triple single pill combination of amlodipine, atorvastatin and perindopril in patients with arterial hypertension (HTN) and dyslipidemia in the daily clinical practice**.**

Do you have to take part?

Your participation in this study is entirely voluntary. It is your choice to take part in this study or not.

If you decide to take part in the study you are still free to withdraw at any time without giving any reason. Your research doctor may ask you the reason for your withdrawal to which you are free to answer or not. Your decision to withdraw will not affect the standard of care you receive and you will continue to receive the same level and quality of medical treatment as before. Any information collected on you up to the point of withdrawal can be used for scientific analysis purpose.

What does this study involve?

During the 12-week observational period, you will continue to be routinely followed-up by your doctor, in accordance with the normal course of your care. Before inclusion in the study you will be prescribed a triple single pill combination of amlodipine, atorvastatin and perindopril according to your doctor's clinical decision.

If you participate in this observational program, you will be appointed to visit your doctor in 1 and 3 months from the start of the study in order to analyse the treatment response. At mentioned visits your doctor will ask you to complete an adherence questionnaire and a questionnaire aimed to assess your quality of life as well as he/she will collect information about any potential side-effect from the treatment you may have received.

What are the possible risks and benefits of taking part in this study?

This study involves collection of information about your health status within routine care only. This study is observational in its nature and there is no direct benefit for you in participation in it however, information collected during this study may help improve the current scientific and medical knowledge upon treatment and nature of arterial hypertension and dyslipidaemia and eventually contribute to better management approaches of these conditions in clinical practice in Russia.

Who is sponsoring this study?

The study is being sponsored by a pharmaceutical company called Servier.

DATA PROTECTION

What personal data are we talking about?

Your personal data may be provided directly by yourself to your research doctor and/or may be collected indirectly (via your medical records).

The categories of personal data collected are as follows: full name, date of birth, age, gender, contact details and health status data.

As to identification data, your full name and contact details and health status data will be known only by your research doctor and the staff / authorised persons from Servier company, who are in charge of controlling the quality of the study. For other people involved in the study (including the sponsor), you will be deidentified by a unique participant number (coded data) without mentioning your name. Your research doctor will securely keep the correspondence table between your name and your participant number (at the research site).

Why do we process your personal data?

Use of your data for the purpose of the study and/or in connection with your disease:

- Your medical records and the data generated during the study will be used for the scientific purpose of the study only. They may be used after the end of the study in connection with your disease.
- The use of your data is mandatory: it is not possible to participate in the study without having your personal data processed.

Use of data for other purposes:

Your coded data may be used after the end of the study to advance science, medicine and public health. In these cases, the data may be shared with private or public third-parties (such as academic, researchers, partners) with appropriate safeguards. In no case neither your name nor any direct identifier will be disclosed. These uses may have to be approved by Ethics Committees and Competent Authorities beforehand.

CONTACTS	
Data Protection Contact *to ask questions and help you exercise your rights*	***Your Research Doctor*** *Include address of healthcare facility and phone number*
Local / National Data Protection Authority *to lodge a complaint regarding the protection of your data*	Federal Service for Supervision of Communications, Information Technology, and Mass Media (Roskomnadzor) 7, bldg. 2 Kitaigorodskiy proezd Moscow, 109992

CONSENT FORM

By signing this consent form, I confirm:

- I have been given a full explanation of the nature, purpose and duration of the study.
- I was able to ask questions regarding all aspects of the study.
- I agree to voluntarily take part in this study.
- I have noted I am free to withdraw from the study at any time if I so desire.
- I express my consent to the processing of my following personal data:
  - Surname, first name, patronymic name
  - Contact details

By the operator:
Full name of the research doctor _____,
Address of healthcare facility _____,
and in accordance with the Federal Law of the Russian Federation No. 152-FZ dated July 27, 2006, other applicable laws and regulations.

- I have been informed that my personal data will be used for the research purpose of the study (including after the completion of the study) "AN AMBISPECTIVE OBSERVATIONAL (NON-INTERVENTIONAL), MULTICENTER STUDY TO DESCRIBE ANTIHYPERTENSIVE AND HYPOLIPIDEMIC EFFECTIVENESS OF A TRIPLE SINGLE PILL COMBINATION OF AMLODIPINE, ATORVASTATIN AND PERINDOPRIL IN PATIENTS WITH ARTERIAL HYPERTENSION (HTN) AND DYSLIPIDEMIA IN THE DAILY CLINICAL PRACTICE" and cannot not be used for any other purpose.
- The present consent is granted to actions performed without automation with the above personal data, including collection, recording, storage, transfer, and use.
- The present consent is valid for fifteen (15) years from the date of signing by the Participant or until the consent is withdrawn, whichever comes first.
- Consent may be withdrawn at any time upon a written request sent to (name of the research doctor) _____ at the address _____; or in electronic form through the website, or by sending an e-mail to address: _____.

PARTICIPANT INFORMATION & CONSENT FORM

Participant

First name and last name	*Date*	*Signature*

Investigator

First name and last name	*Date*	*Signature*

Witness(es) (if applicable)

First name and last name	*Date*	*Signature*

Give one signed original information and consent form to the participant and keep the other signed original in the study file.