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Russian observational program ODA

Submission date 17/05/2017	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/05/2017	**Overall study status** Completed	
Last Edited 10/10/2022	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Chronic stable angina is a common symptom of heart disease that causes pain or discomfort in the chest. Medical treatments are the main approach to try to reduce the rate of angina. Angina can have a major impact on patient quality of life and puts a high financial and medical burden on society. Given the range of treatments now available, optimal medical therapy, which according to International and National guidelines for patients' treatment is the preferred option in the majority of patients with heart disease and angina, offers the opportunity for effective control. However, recent studies have suggested that up to a third of patients are not managing there symptoms and that physicians often underestimate how much angina continues to limit patients' lives. Approximately 50% of patients with cardiovascular disease and/or its major risk factors have a hard time adhering (sticking to their) prescribed medications. Finding new methods to help patients improve their adherence can help improve their quality of life greatly. Preductal® OD 80 mg is a delayed release medication containing the ingredient trimetazidine which allows patients to only have to take it once a day. The reason for developing a medication that delays the release of the ingredients is to improve patient's comfort and compliance, by offering the a once a day formulation in comparison. The aim of this study is to analyze effectiveness and tolerability of Preductal® OD 80 mg use in symptomatic patients with angina pectoris over a 3-month treatment under daily practice conditions.

Who can participate?
Adults aged between 18 to 75 years old with a confirmed diagnosis of chronic coronary artery disease and stable angina.

What does the study involve?
This study is a observational study that uses data from participants who are prescribed the Preductal® OD 80 mg treatment by a physician and who have consent to participate in this study. Participants attend an initial study sessions where the study team collects data about their number of angina attacks, and evaluates their symptoms. They then begin their treatment as prescribed by their physician. Participants attend follow up visits one month and three months after taking the medication where they then provide data about the number of angina attacks and their symptoms as well as adherence to the treatment and any adverse drug reactions. At the last study visit (after three months of taking the medication), participants undergo a general assessment for the effectiveness of the treatment.
What are the possible benefits and risks of participating?

The positive benefit-risk balance of trimetazidine in stable angina was recently reaffirmed in an assessment of the European Medicines Agency in 2012.

Where is the study run from?
I.M. Sechenov First Moscow State Medical University (Russia)

When is the study starting and how long is it expected to run for?
August 2016 to August 2017

Who is funding the study?
Servier (Russia)

Who is the main contact
Mrs Anna Davydova

Contact information

Type(s)
Scientific

Contact name
Mrs Anna Davydova

Contact details
JSC Servier
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125047

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DIM-06795-001-RUS

Study information

Scientific Title
Evaluation of effectiveness and therapeutic response to Preductal OD 80 mg in daily practical use for chronic stable angina pectoris

Acronym
ODA

Study objectives
The aim of this study is to analyze the effectiveness and tolerability of Preductal® OD 80 mg usage in symptomatic patients with angina pectoris over a 3-month treatment under daily practice conditions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Межвузовский комитет по этике (Intercollegiate Ethics Committee), 14/12/2016. ref: Statement N 10-16 17.11.2016

Study design
Non-interventional observational multicentric prospective study

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Chronic coronary artery disease and stable angina

Interventions
This a non-interventional study. Participants are included in this study is they have a confirmed diagnosis of chronic coronary artery disease and stable angina and have been determined by a physician regarding the medical meaningfulness and necessity of treatment with with Preductal® OD 80 mg. Participants also sign informed consent. Participants physician makes adjustments to the therapy in patients with persistent angina after the failure of previous treatment, according to his/her personal experience and current medical practice, as well as to indications and dosages stated in the instructions for use (SPCs) for the corresponding medication.

In case of therapy adjustment at the moment of inclusion the physician has to specify both treatments before inclusion and modifications made at the moment of inclusion in the study.

Participants are examined three times, first at an baseline (inclusion visit), at one month (second (control) visit) and then three months for a final visit (or if they withdraw from taking the medication).

At each of the study visits, participant data is collected to measure the number of angina attacks, number of uses of short-acting nitrates, evaluation of symptomatic status (physician assessment), self-assessment of their daily activity, and compliance/adherence. Any adverse drug reactions/events are collected at the second and third visit. Participants undergo a general assessment for Preductal OD 80 mg therapy by their physician at the last study visit. All examinations in the context of this study are to be performed if they take place in the framework of routine diagnostic and therapeutic procedures. Procedures that are out of the usual medical routine are prohibited.

Observational follow-up time per patient will be approximately three months.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Preductal® OD (trimetazidine)

Primary outcome measure
1. Number of angina attacks is measured using the patient interviews at baseline, one and three months
2. Use of short-acting nitrates is measured using the patient interviews at baseline, one and three months
3. Symptomatic classification measured is measured using Canadian Cardiovascular Society Classification of Symptoms of Angina at baseline, one and three months
4. Daily activity is measured by patients using visual scale at baseline, one and three months

Secondary outcome measures
1. Patients' compliance/adherence is measured using questionnaire at baseline, one and three months
2. General tolerance and adverse events (AE) / adverse drug reactions (ADR) under Preductal® OD 80 mg therapy is measured using Adverse event / Adverse drug reaction / Special situation form collection at one and three months
3. Clinical assessment in symptomatic patients with angina pectoris is measured using questionnaire at month three

Overall study start date
25/08/2016

Completion date
31/08/2017

Eligibility

Key inclusion criteria
1. Confirmed diagnosis of Chronic Coronary Artery Disease and stable angina. Special care has to be taken that inclusion of patients into the non-interventional study is exclusively determined by the decision of the physician regarding medical meaningfulness and necessity of treatment with

Preductal® OD 80 mg.
2. Signed informed consent
3. Aged 18 to 75 years old

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
4,000 (planned)

Total final enrolment
3032

Key exclusion criteria
1. Age over 75 years or under 18 years
2. Hypersensitivity to the active substance or to any of the excipients listed in Preductal® OD 80 mg SmPC
3. Parkinson disease, parkinsonian symptoms, tremors, restlessleg syndrome, and other related movement disorders
4. Severe renal impairment (creatinine clearance < 30ml/min)
5. Moderate renal impairment (creatinine clearance [30-60] ml/min)
6. Stable angina pectoris FC IV
7. Myocardial Infarction (MI) in the last 3 months before inclusion
8. Stroke/TIA in the last 3 months before inclusion
9. Uncontrolled HT (BP over 180/100 mm Hq) inspite of hypotensive therapy
10.Pregnancy or breastfeeding

Date of first enrolment
08/03/2017

Date of final enrolment
31/05/2017

Locations

Countries of recruitment
Russian Federation

Study participating centre

I.M. Sechenov First Moscow State Medical University
Malaya Trubetskaya ul 8
Moscow
Russian Federation
119991

Sponsor information

Organisation
JSC Servier

Sponsor details
Lesnaya 7
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125047

Sponsor type
Other

ROR
https://ror.org/034e7c066

Funder(s)

Funder type
Industry

Funder Name
Servier

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/08/2018

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2018		Yes	No
Results article	results	01/06/2019		Yes	No
Results article	results	01/12/2020	26/05/2020	Yes	No
Protocol file			10/10/2022	No	No