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Assessment of the efficacy and tolerability of Preductal OD and its influence on quality of life when added to bisoprolol in patients with stable angina

Submission date
03/09/2021

Recruitment status
No longer recruiting

Registration date
08/09/2021

Overall study status
Completed

Last Edited
30/12/2021

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Angina is chest pain caused by reduced blood flow to the heart muscles. It's not usually life threatening, but it's a warning sign that you could be at risk of a heart attack or stroke. With treatment and healthy lifestyle changes, it's possible to control angina and reduce the risk of these more serious problems.
The main medicines used to prevent angina attacks are:
beta blockers – to make the heart beat slower and with less force
calcium channel blockers – to relax the arteries, increasing blood supply to the heart muscle
Bisoprolol is a medicine used to treat high blood pressure (hypertension) and heart failure. If you have high blood pressure, taking bisoprolol helps prevent future heart disease, heart attacks and strokes. Bisoprolol is also used to prevent chest pain caused by angina.
Trimetazidine (Preductal) is a medicine used to prevent angina attacks.

The aim of this study was to evaluate the efficacy, tolerability, and also the influence on quality of life of the drug Preductal in patients with coronary artery disease (CAD) and angina pectoris during a 3-month treatment in combination with bisoprolol.

Who can participate?
Adult patients over 18 years of age with a confirmed diagnosis of stable angina.

What does the study involve?
Patients were treated in line with current recommendations for CCS management, which had to include receiving the maximal tolerated dose of bisoprolol. They could also be receiving a range of other cardiovascular drugs including calcium channel blockers, diuretics, angiotensin-converting enzyme inhibitors, and angiotensin receptor blockers, and imidazole receptor agonists. Follow up was 3 months.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Servier (Russia)

When is the study starting and how long is it expected to run for?
October 2017 to July 2018

Who is funding the study?
Servier (France)

Who is the main contact?
Prof. Yuriy Lopatin, yumlopatin@volgmed.ru

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
№ IC4-06795-051-RUS

Study information

Scientific Title
Evaluation of the efficacy, tolerability, and also the influence on quality of life of the drug Preductal OD, 80 mg sustained-release capsules (JSC Servier, Russia) in patients with coronary

artery disease (CAD) and angina pectoris during a 3-month treatment in combination with bisoprolol in an outpatient setting

Acronym
MODUS VIVENDI

Study objectives
The aim of the multicenter observational uncontrolled study was to evaluate the efficacy, tolerability, and also the influence on quality of life of the drug Preductal OD, 80 mg sustained-release capsules (JSC Servier, Russia) in patients with coronary artery disease (CAD) and angina pectoris during a 3-month treatment in combination with bisoprolol in an outpatient setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/12/2017, Local Institutional Ethics Committee (Moscow, Gagarinskiy st. 37/2, Russia; +8-916-260-76-64; ethicano@yahoo.com), ref: Protocol #11-17

Study design
Multicenter prospective open-label uncontrolled observational study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Coronary artery disease

Interventions
General practitioners and cardiologists with outpatient practices included adult patients >18 years of age with a confirmed diagnosis of stable angina (defined as class II-III angina according to the Canadian Cardiovascular Society [CCS] classification). Patients were treated in line with current recommendations for CCS management, which had to include receiving the maximal tolerated dose of bisoprolol.

Subjects were requested to make three visits to the study site: an inclusion visit (V1) at which patients were prescribed TMZ 80 mg once daily; a 1-month follow-up visit (V2); and a 3-month follow-up visit (V3). At each visit the following information was collected: data on number of angina attacks and number of short-acting nitrate doses taken (based on patient diary); quality-of-life assessments using the EuroQol 5 Dimensions 3 Levels (EQ-5D-3L) questionnaire and a visual analoganalogue scale (VAS); and assessment of medication adherence. Information on spontaneously reported adverse drug reactions or events was collected at the V2 and V3 visits.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Trimetazidine - Preductal OD 80mg (Vastarel OD 80mg)

Primary outcome(s)
Measured throughout the study using patient records (up to 3 months):
1. Number of angina attacks per week
2. Number of consumed short-acting nitroglycerin preparations per week.

Key secondary outcome(s))
1. The rates of reported adverse events, including serious adverse events, were analyzed using patient records up to 3 months
2. The quality of life of patients was evaluated according to the results of the EQ-5D-3L questionnaire and visual analogue scale (VAS) at baseline, 1 and 3-months

Completion date
27/07/2018

Eligibility

Key inclusion criteria
1. Confirmed diagnosis of CAD, class II or III stable angina
2. Treatment with bisoprolol
3. Signed informed consent of a patient
4. No contraindications to the prescription of PREDUCTAL as indicated in the instruction for use of medicinal product for medical purposes

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
1939

Key exclusion criteria
1. Age below 18 years
2. Class IV stable angina
3. Unstable angina
4. Myocardial infarction within 3 months prior to the inclusion in the program
5. Cerebrovascular accident (stroke of various cause; TIA) within 3 months prior to the inclusion in the program
6. Uncontrolled arterial hypertension (BP above 180 and 100 mm Hg), despite the current

antihypertensive treatment.
7. Pregnancy, breastfeeding.
8. Inability to understand the nature of the program and follow the recommendations.
9. Presence of contraindications or known intolerance to trimetazidine.

Date of first enrolment
24/12/2017

Date of final enrolment
27/05/2018

Locations

Countries of recruitment
Russian Federation

Study participating centre
ГБУЗ ГП № 22 ДЗМ филиал № 1 (ГП № 10)
st. Tsyurupy, 30/63
Moscow
Russian Federation
117418

Study participating centre
Ярославская ЦРБ (Central Hispital of Yaroslavl)
Yaroslavsky District, D. Karabikha, Str. Hospital Town, D. 1 A
Yaroslavl
Russian Federation
150522

Study participating centre
ГБУЗ «Городская поликлиника №49»
st. Lanskaya, 12
St. Petersburg
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197343

Study participating centre
Мурманск Городская поликлиника №2
st. Lobova, 65
Murmansk
Russian Federation
183017

Study participating centre
Краснодар поликлиника № 25
Plane Boulevard, 10 / A.
Krasnodar
Russian Federation
350089

Study participating centre
Поликлиника №50
Gornaya St. 15
Nizhny Novgorod
Russian Federation
603079

Study participating centre
ОКБ №3, поликлиника №2
Victory Avenue 376
Chelyabinsk
Russian Federation
454021

Study participating centre
Городская поликлинка 29 Новосибирск
st. Rassvetnaya, 1
Novosibirsk
Russian Federation
630129

Sponsor information

Organisation
Servier (Russia)

Funder(s)

Funder type
Industry

Funder Name
Servier

Alternative Name(s)
Servier Laboratories, Laboratoires Servier

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
France

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/12/2021	30/12/2021	Yes	No
Participant information sheet			08/09/2021	No	Yes