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RESPONSIfVE: efficacy and therapeutic response to Procoralan® in the treatment of chronic stable angina pectoris in routine medical practice

Submission date
24/01/2013

Recruitment status
No longer recruiting

Registration date
15/02/2013

Overall study status
Completed

Last Edited
11/01/2019

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Coronary heart disease is the leading cause of death in Germany. The main symptoms are angina (chest pain), heart attacks and heart failure. Procoralan® (ivabradine) is a drug that is used instead of or in combination with beta blockers to treat angina and reduce heart rate. The aim of this study is to gather information on the effectiveness and tolerance of Procoralan® treatment either in combination or not with beta blockers. Information is to be gathered regarding the effect of Procoralan® on angina and resting heart rate, on possible interactions between Procoralan® and other medications, and adverse drug reactions.

Who can participate?
Patients with angina who are to be treated with Procoralan® either in combination or not with a beta blocker

What does the study involve?
Procoralan® is given to participants according to the usual procedure. Three examinations are planned during routine treatment: an examination at the start of the treatment, a check-up examination after about one month of treatment, and a final examination either at the end of treatment or after about four months of treatment. Information is collected on medical history, other medications and diseases, heart rate and blood pressure.

What are the possible benefits and risks of participating?
The study does not affect the regular treatment of patients and all examinations and medical procedures do not exceed the normal procedure of treatment. Patients are therefore not exposed to any additional risks.

Where is the study run from?
Servier Deutschland GmbH (Germany)

When is the study starting and how long is it expected to run for?
March 2013 to September 2013

Who is funding the study?
Servier Deutschland GmbH (Germany)

Who is the main contact?
1. Dr Martin Kühn
2. Dr Stefan Perings

Contact information

Type(s)
Scientific

Contact name
Dr Martin Kühn

Contact details
Elsenheimer Str. 53
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80687

Additional identifiers

Protocol serial number
IC4-16257-132-DEU

Study information

Scientific Title
RESPONSIfVE: efficacy and therapeutic response to Procoralan® in the treatment of chronic stable angina pectoris in routine medical practice a prospective non-interventional study

Study objectives
The study aims at gaining information on efficacy and tolerance of Procoralan® treatment (as proven in clinical trials) either in combination or not with beta blockers in patients under daily routine medical procedures.

Additional information is sought on the percentile distribution of patients who's heart rate is reduced to less than 70 bpm or who's heart rate is reduced by at least 10 bpm (responder analysis).

Supplementary information is to be gained regarding influence of Procoralan® therapy on angina pectoris symptoms and resting heart rate, on possible correlations between Procoralan® and various pre- and concomitant medications, on possible adverse drug reactions and on administration of Procoralan® in accordance to summary of product information and routine medical practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Freiburg Ethics Commission International, 14/01/2013

Study design
Multi-center prospective non-interventional study (post-marketing authorisation)

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic stable angina pectoris/cardiology

Interventions
Participating physicians receive a spiral folder including the complete documents for four patients with chronic stable angina pectoris who are to be treated routinely with Procoralan® . Data will be documented at four planed examinations. The exact dates are set according to routine medical procedure of the attending physician.
At baseline examination (U1; at the beginning of treatment) data will be documented on:
1. Date of examination
2. Patient data (age, gender, height, weight)
3. Anamnesis (duration and type of coronary heart disease, duration of chronic stable angina pectoris, CCS-classification, data on myocardial infarctions)
4. Further cardiac findings (chronic cardiac insufficiency, NYHA-classification, left-ventricular dysfunction, cardiac valvular defects) preceding therapies (PCI, CABG, cardiac pacemaker implantation)
5. Cardiovascular risk factors (genetic disposition, arterial hypertonia, diabetes mellitus, adiposity, dyslipidemia, nicotine abuse, elevated resting heart rate (>70 bpm)
6. Concomitant diseases (status post stroke, TIA, asthma, COPD, depression, sleep apnea, nephropathy, PVD, thyroid disease, other)
7. Use of beta blockers (current therapy, start of therapy, contraindications or intolerance to beta blockers such as asthma, hypotonia, arterioventricular conduction disturbances, bradycardia, COPD, erectile dysfunction, tiredness/fatigue, intake of calcium channel blockers (type verapamil/diltiazem), other), other cardiovascular medication (ACE-inhibitor, AT1-receptor antagonist, aldosterone antagonist, long-acting nitrates, ranolazine, molsidomine, calcium antagonists (type verapamil/diltiazem or dihydropyridine), NSAIDs, clopidogrel/prasugrel /ticagrelor, other platelet aggregation inhibitors, statine, diuretics, anti arrhythmic agents, other antilipemics)
8. Further concomitant medication (oral diabetics, insulin, anti depressants, oral anticoagulants, thyroxin, ulcer therapeutics, COPD-medication, medication for asthma, other medication)
9. Actual findings (heart rate, blood pressure, frequency of occurred angina pectoris episodes and usage of short-acting nitrates over the past seven days), Procoralan® therapy (patient classification, intended dose)

Data on examination 2 (U2, approximately one month following therapy start):
1. Date of examination

2. Information on continuation/discontinuation/change in dose of Procoralan® therapy
3. Information on possibly occurred adverse drug reactions or adverse reactions leading to termination of Procoralan® therapy
-information on changes in therapy with beta blockers or pharmaceutical treatment of stable angina pectoris
4. Actual findings (heart rate, blood pressure, frequency of occurred angina pectoris episodes and usage of short-acting nitrates over the past seven days)

Data on examination 3 (U3, approximately four months post start of therapy or at termination of Procoralan® therapy)
1. Date of examination
2. Information on continuation/discontinuation/change in dose of Procoralan® therapy
3. Information on possibly occurred adverse drug reactions or adverse reactions leading to termination of Procoralan® therapy
4. Information on changes in therapy with beta blockers or pharmaceutical treatment of stable angina pectoris
5. Actual findings (heart rate, blood pressure, frequency of occurred angina pectoris episodes and usage of short-acting nitrates over the past seven days, CCS-classification, NYHA-classification, left ventricular dysfunction)
6. Assessment of Procoralan® (efficacy, tolerance)
7. Possibly occurred particularities under Copaxone® (over dose, pregnancy)

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Ivabradine

Primary outcome(s)
The study aims at gaining information on efficacy and tolerance of Procoralan® treatment (as proven in clinical trials) either in combination or not with beta blockers in patients under daily routine medical procedures.
Additional information is sought on the percentil distribution of patients who's heart rate is reduced to less than 70 bpm or who´s heart rate is reduced by at least 10 bpm (responder analysis).

Key secondary outcome(s))
Supplementary information is to be gained regarding:
1. Influence of Procoralan® therapy on angina pectoris symptoms and resting heart rate
2. On possible correlations between Procoralan® and various pre- and concomitant medications
3. On possible adverse drug reactions
3. On administration of Procoralan® in accordance to summary of product information and routine medical practice

Completion date
30/09/2013

Eligibility

Key inclusion criteria
1. Adult patients, either sex, with chronic stable angina pectoris
2. who are to be routinely treated with Procoralan®, regarding the summary of product characteristics, either in combination or not with beta blocker medications.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
All contraindications listed in summary of product characteristics.

Date of first enrolment
01/03/2013

Date of final enrolment
31/05/2013

Locations

Countries of recruitment
Germany

Study participating centre
Elsenheimer Str. 53
München
Germany
80687

Sponsor information

Organisation
Servier Deutschland GmbH (Germany)

ROR
https://ror.org/05wk4ae67

Funder(s)

Funder type
Industry

Funder Name
Servier Deutschland GmbH (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2016	11/01/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes