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RELIf-CHF: Longterm treatment with ivabradine in ambulatory patients with chronic systolic heart failure

Submission date	Recruitment status	[_] Prospectively registered
11/03/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/04/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/01/2019	Circulatory System	

Plain English summary of protocol

Background and study aims
Chronic systolic heart insufficiency is currently the most common cause for hospitalisation in Germany. This will increase in the future due to aging populations in developed countries. Procoralan® (ivabradine) is indicated for treating chronic stable angina pectoris in adult patients with coronary heart disease and normal sinus rhythm in patients with intolerance or contraindications to beta blockers or in combination with beta blockers in patients with a heart rate >60 bmp, who are still not sufficiently adjusted while being on an optimal dose of beta blockers. Procoralan® is also indicated for treating chronic cardiac insufficiency in patients with systolic dysfunction, with a normal sinus rhythm and a heart rate ≥ 75 bpm. The aim of this study is to analyse the use and tolerability of Procoralan® in patients with chronic systolic heart insufficiency.

Who can participate?
About 2250 ambulatory patients of either sex, suffering from chronic systolic heart insufficiency and who are prescribed Procolaran.

What does the study involve?
Doctors will collect information during 5 routine visits (at the start of the study, after 1, 4, 8 and 12 months). Patients will be asked to fill in a quality of life at visit 1, 3 and 5.

What are the possible benefits and risks of participating?
There will not be any special benefits. The study does not influence regular treatment as all examinations and medical procedures do not exceed routine therapy. Patients are therefore not exposed to any additional risks.
Potential adverse drug reactions and adverse reactions leading to termination of Procoralan® therapy, pregnancies and overdoses must be reported to drug safety department of Servier Forschung und Pharmaentwicklung GmbH (Fax: +49-89-57095-100) within 24 hours. Collected data will be evaluated and published.

Where is the study run from?
From 750 internal specialists (cardiology) located throughout Germany.

When is the study starting and how long is it expected to run for?
The study is expected to start in March 2014 and to end in June 2015. There will be a 3-month recruitment period and a 12-month observation period per patient

Who is funding the study?
Servier Deutschland GmbH

Who is the main contact?
Dr. Kühn, head of medical affairs at Servier Deutschland GmbH
Dr. Zugck, scientific coordinator

Contact information

Type(s)
Scientific

Contact name
Dr Martin Kühn

Contact details
Servier Deutschland GmbH
Elsenheimerstr. 53
Munich
Germany
80687

Additional identifiers

Protocol serial number
IC4-16257-146-DEU

Study information

Scientific Title
RELIf-CHF: Longterm treatment with ivabradine in ambulatory patients with chronic systolic heart failure - a prospective non-interventional study

Study objectives
The non-interventional study (NIS) aims at gaining information on Procoralan® efficacy in ambulatory patients with chronic systolic heart insufficiency under existing medical concomitant therapy for heart insufficiency under routine conditions. Changes in heart frequency, therapy influence on symptom control, life quality and patients rate of hospitalisation and assessment of general tolerance are of particular interest. In addition, information on specific adverse drug reactions under Procoralan® therapy are to be collected.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Freiburg Ethics Commission International, 03/03/2014, ref. 014/1161

Primary study design
Observational

Study design
Non-interventional study [according to AMG 4 (23) sentence 3] prospective open multicentric

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic systolic heart insufficiency/cardiology

Interventions
Participating physicians receive a spiral folder including documents for 3 patients. Data will be collected at 5 examinations during routine medical treatment.
Following data will be collected:
Inclusion visit U1 (at start of therapy)
1. Patient information and written informed consent
2. Handout of EQ-5D health questionnaire
3. Demographic data: age, size, weight, sex
4. Special anamnesis: duration of heart insufficiency, heart insufficiency etiology, ECG
5. Risk factors, concomitant diseases
6. Beta blocker therapy
7. Other pharmacological (cardiovascular) adjunctive therapy
8. Documentation of heart insufficiency: NYHA-classification, LV-EF, blood pressure, heart frequency at rest, signs of decompensation, BNP, hospitalisation due to heart insufficiency in the last 12 months
9. Therapy with Procoralan®: Reason for adjustment, therapy start, dosage

Control examination U2 (approx. after 1 month), U3 (approx. after 4 months) and U4 (approx. after 8 month)
1. Only U3: Handout of EQ-5D health questionnaire
2. Documentation of heart insufficiency: NYHA-classification, LV-EF, blood pressure, heart frequency at rest, signs of decompensation, BNP, hospitalisation due to heart insufficiency since the last examination
3. Dosage, therapy cange of Procoralan®
4. Change of beta blocker therapy
5. Change of other pharmacological (cardiovascular) adjunctive therapy
6. Tolerability (AE/ADR)

Final examination U5 (approx. after 12 months)
1. Handout of EQ-5D health questionnaire
2. Documentation of heart insufficiency: NYHA-classification, LV-EF, blood pressure, heart frequency at rest, signs of decompensation, BNP, hospitalisation due to heart insufficiency since the last examination
3. Dosage, therapy change, continuation of therapy with Procoralan®
4. Change of beta blocker therapy

5. Change of other pharmacological (cardiovascular) adjunctive therapy
6. Final physicians assessment of Procoralan® therapy
7. Tolerability (AE/ADR)

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Use and tolerance of Procoralan® in accordance with the SmPC
2. The effect of treatment on symptoms of chronic systolic heart failure in ambulatory patients non-interventional under routine daily conditions

Measurement of outcomes (efficacy and safety under medical routine treatment) at the following 5 time points:
Baseline (U1)/start of therapy, after 4 weeks (U2), after 4 months (U3), after 8 month (U4), after 12 month (U5)

Key secondary outcome(s)
1. Changes in heart frequency during treatment with Procoralan®
2. Therapy influence on symptom control: NYHA classification, decompensation
3. Influence of therapy on life quality and patients´ hospitalisation rate
4. Assessment of possible correlations of Procoralan® therapy and existing (cardiovascular) concomitant therapy
5. Adding of knowledge regarding general tolerance and specific adverse drug reactions (ADR) under Procoralan® therapy
6. General assessment of Procoralan® therapy in patients with chronic systolic heart insufficiency under existing medical concomitant therapy for heart insufficiency

Completion date
17/06/2015

Eligibility

Key inclusion criteria
Ambulant patients with chronic systolic heart insufficiency, who are treated according to the indication of Procoralan®. This includes:
1. Patients with chronic heart failure NYHA II to IV with systolic dysfunction
2. Patients with chronic heart failure with sinus rhythm and whose heart rate is ≥ 75 bpm in combination with standard therapy in-/excluding beta-blocker therapy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Sex
All

Key exclusion criteria
All contraindications listed in the Summary of Product Characteristics (SmPC)

Date of first enrolment
17/03/2014

Date of final enrolment
17/06/2015

Locations

Countries of recruitment
Germany

Study participating centre
Servier Deutschland GmbH
Munich
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	01/08/2017	11/01/2019	Yes	No