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INTENSIFY: PractIcal daily effectiveNess and TolEraNce of Procoralan® in chronic SystolIc heart Failure in GermanY

Submission date	Recruitment status	[_] Prospectively registered
07/05/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/06/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/01/2019	Circulatory System	

Plain English summary of protocol

Background and study aims
Chronic heart failure is currently the most frequent cause of hospitalization in Germany. Despite being treated with a wide range of drugs known as beta-blockers, many heart failure patients still have insufficient heart rate reduction. Heart failure patients should generally be controlled for heart rate as it is an important risk factor for cardiovascular death. The aims of this study is to observe the effects of Procoralan®, a drug that specifically reduces heart rate, on heart failure symptoms, heart rate reduction and quality of life in patients with chronic stable heart failure under daily routine. We also intend to assess how safe and tolerated this drug is.

Who can participate?
Ambulatory patients (who can walk), with no age and gender limitation, with stable chronic heart failure and resting heart rate ≥ 75 beats per minute, who have been prescribed Procoralan® before entering the study.

What does the study involve?
All patients involved in the study will be treated with Procoralan®. They will be asked to come to follow up visits after four weeks and then after another three months. During these visits a routine practice investigation will be carried out and a case report form regarding heart failure, co-medications and other diseases will be filled out by the doctor. The patients will be asked to fill out the patient quality of life questionnaire (EQ-5D) at each visit. According to heart rate reduction, the dosage of Procoralan® can be adapted at the first follow-up visit (week 4). Patients will be included in the study for four months.

What are the possible benefits and risks of participating?
There are no particular benefits or risks. The treatment given to the patient corresponds to the daily routine. Patients are free to withdraw from the study at any time without giving a particular reason.

Where is the study run from?
It is planned that the study will be carried out by approximately 1000 cardiologists and internists (practice-based or in outpatient clinics) across the Germany. There is no lead center.

When is the study starting and how long is it expected to run for?
The study starts on 19th April 2012 and lasts until 31st December 2012. The recruitment of participants runs until 31st July 2012.

Who is funding the study?
The funder and the sponsor of the study is Servier Deutschland, GmbH.

Who is the main contact?
Dr Peter Martinka
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
IC4-16257-131 DEU

Study information

Scientific Title
INTENSIFY: PractIcal daily effectiveNess and TolEraNce of Procoralan® in chronic SystolIc heart Failure in GermanY: An observational prospective multicentre study

Acronym
INTENSIFY

Study objectives
Effects of therapy with Procoralan® (Ivabradine) on heart failure symptoms and quality of life in patients with stable chronic systolic heart insufficiency under daily routine in an observational prospective multicentre trial by cardiologists, internists and general practitioners.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Medical Faculty University of Heidelberg, 12/03/2012

Study design
Observational prospective multicentre open-label study

Primary study design
Observational

Secondary study design
Other

Study setting(s)
Hospital

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 stable systolic heart insufficiency

Interventions
Observational study to get information about therapy of chronic systolic heart insufficiency with Procoralan®; under daily routine practice by cardiologists, internists and general practitioners.

The diagnosis of angina will be confirmed by trialists at baseline. After the baseline visit, there is a visit after 4 weeks and the final visit after 4 months.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Procoralan® ((ivabradine)

Primary outcome measure

1. Change in heart failure symptoms and left ventricular function
2. Effects of therapy on quality of life assessed by EQ-5D
3. Effects of therapy on resting heart rate
4. Information about how Procoralan® SmPC and patients information are followed via standardised documentation of the dosage of Procoralan®, of comedications and concomitant diseases
5. Analysis of general tolerability of Procoralan® under routine conditions via standardised adverse reactions documentation and standardised documentation of therapy discontinuation
6. Analysis of unknown adverse drug reactions via standardised documentation

Secondary outcome measures
No secondary outcome measures

Overall study start date
19/04/2012

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Adult patients (male, female) with chronic systolic heart insufficiency
2. New York Heart Association (NYHA)-Class II-IV, with resting heart rate superior or equal to 75

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
3570

Key exclusion criteria
1. Does not meet inclusion criteria
2. Investigators should follow the Summary of Product Specifications (SmPC) of Procoralan®, which include the following contraindications:
2.1. Hypersensitivity to the active substance or to any of the excipients
2.2. Resting heart rate below 60 beats per minute prior to treatment
2.3. Cardiogenic shock
2.4. Acute myocardial infarction
2.5. Severe hypotension (< 90/50 mmHg)
2.6. Severe hepatic insufficiency
2.7. Sick sinus syndrome
2.8. Sino-atrial block
2.9. Unstable or acute heart insufficiency

2.10. Pacemaker dependent
2.11. Unstable angina
2.12. Atrioventricular (AV) block of 3rd degree
2.13. Combination with strong cytochrome P450 3A4 inhibitors such as azole antifungals (ketoconazole, itraconazole), macrolide antibiotics (clarithromycin, erythromycin per os, josamycin, telithromycin), Human immunodeficiency virus (HIV) protease inhibitors (nelfinavir, ritonavir) and nefazodone
2.14. Pregnancy, lactation

Date of first enrolment
19/04/2012

Date of final enrolment
31/07/2012

Locations

Countries of recruitment
Germany

Study participating centre
Servier Deutschland GmbH
München
Germany
80687

Sponsor information

Organisation
Servier Deutschland GmbH (Germany)

Sponsor details
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Sponsor type
Industry

Website
http://www.servier.com/

ROR
https://ror.org/05wk4ae67

Funder(s)

Funder type
Industry

Funder Name
Servier Deutschland GmbH (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from SERVIER Deutschland GmbH, Dr Georg Stöckl, Elsenheimerstraße 53, 80687 München, Germany, Tel: +49 (0)89 570 95 246.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2014		Yes	No