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ADDITIONS: Practical daily efficacy and safety or Procoralan® in combination with betablockers

Submission date	Recruitment status	[_] Prospectively registered
15/03/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/06/2017	Circulatory System	

Plain English summary of protocol
Not provided at time of registration and not expected to be available in the future

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
IC4-16257-105-DEU

Study information

Scientific Title
ADDITIONS: Practical daily efficacy and safety or Procoralan® in combination with betablockers: Observational prospective multicentre study

Acronym
ADDITIONS

Study objectives
Effects of therapy with Procoralan® in combination with betablockers on angina symptoms in patients with stable angina pectoris under daily routine in an observational prospective multicentre trial by general practioners, internists and cardiologists.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Martin-Luther University Halle-Wittenberg, 23/02/2010

Study design
Observational prospective multicentre study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Stable angina pectoris

Interventions
Observational study to get information about therapy with Procoralan® in combination with betablockers under daily routine practice by general practitioners, internists and cardiologists.

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.
For the follow up there are additional visits after 8 and 12 months.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Change in angina symptoms (number of angina attacks, consumption of short acting nitrates per week)
2. Effects of the therapy on quality of life via patients questionaire (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
None

Overall study start date
08/03/2010

Completion date
30/05/2011

Eligibility

Key inclusion criteria
Adult patients, either sex, with stable angina pectoris and on betablocker therapy prior to inclusion

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
6000

Key exclusion criteria
1. Does not meet inclusion criteria
2. In addition, doctors involved in the trial should follow the Summary of Product Characteristics (SmPC) for Procoralan®, which includes 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. Heart failure patients with New York Heart Association (NYHA) functional classification III-IV
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), HIV protease inhibitors (nelfinavir, ritonavir) and nefazodone
2.14. Pregnancy, lactation

Date of first enrolment
08/03/2010

Date of final enrolment
30/09/2010

Locations

Countries of recruitment
Germany

Study participating centre
Elsenheimerstr: 53
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Germany
80687

Sponsor information

Organisation
Servier Deutschland GmbH (Germany)

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Sponsor type
Industry

Website
http://www.servier.com/

ROR
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Funder(s)

Funder type
Industry

Funder Name
Servier Deutschland GmbH (Germany)

Results and Publications

Publication and dissemination plan

Intention to publish date

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	01/05/2012		Yes	No
Results article	results	01/02/2015		Yes	No