

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

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

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

Protocol serial number

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

Primary study design

Observational

Study design

Observational prospective multicentre study

Study type(s)

Treatment

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(s)

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 questionnaire (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

Key secondary outcome(s)

None

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

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

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