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An observational study looking at the effects of treating angina pectoris with IMPLICOR® (Metoprolol/ivabradine)

Submission date
19/10/2015

Recruitment status
No longer recruiting

Registration date
28/10/2015

Overall study status
Completed

Last Edited
15/08/2019

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 (CHD), also known as ischemic heart disease, is one of the leading causes of death, both in Germany and worldwide. CHD develops because of the build-up of fatty deposits (plaque) on the walls of the coronary arteries (the arteries that supply the heart with oxygen-rich blood). When arteries are blocked or narrowed, the heart does not receive enough blood to function properly, which can cause pain and tightness in the chest (angina). There are several types of angina, the most common being stable angina pectoris (AP). When you exercise or become stressed, the heart needs to work harder in order to pump enough oxygen around the body. When a person is suffering from AP, this extra stress on the heart causes severe pain in the chest. This type of angina is usually treated using medications and changing a person's lifestyle so that they do not put unnecessary strain on the heart. There is a wide range of drugs which can be prescribed to help people with AP (anti-anginal agents). IMPLICOR® is a newly developed anti-anginal agent which combines two different drugs which are commonly used to treat angina: ivabradine (which slows the heart rate by affecting the electrical activity in the heart) and metoprolol (which "blocks" the effect of adrenaline from speeding up the heart rate). The aim of this study is to find out whether IMPLICOR® is an effective treatment for stable AP.

Who can participate?
Adults suffering from stable angina pectoris who are starting treatment with IMPLICOR®.

What does the study involve?
Patients with chronic (long-term) stable angina pectoris who are going to be treated with IMPLICOR® are asked if they would like to take part in the study. Participants attend regular follow-up appointments for four months while they are taking the medication. At one month and four months, patients have their heart rate measured and are interviewed to find out how many angina attacks they have had, if they have had to be admitted to hospital, and any side effects they are experiencing.

What are the possible benefits and risks of participating?
A potential benefit of taking part in the study is that the treatment may help to improve

participants' angina symptoms. There are no significant risks of participating, although there is a minor risk of side-effects from the medications.

Where is the study run from?
Heart Center of the University of Rostock (Germany)

When is the study starting and how long is it expected to run for?
November 2015 to May 2016

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

Who is the main contact?
Dr Georg Stöckl

Contact information

Type(s)
Scientific

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Dr Georg Stöckl

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
IC4-05154-173-DEU

Study information

Scientific Title
IMPLICOR®-NOW: IMPLICOR® Non-interventional, Observational study With metoprolol /ivabradine fixed combination

Acronym
IMPLICOR®-NOW

Study objectives
The aim of this non-interventional study (NIS) is to analyze application, effectiveness and tolerability of fixed combination IMPLICOR® (Metoprolol/Ivabradine) in symptomatic patients with angina pectoris over a 4-month treatment under daily practice conditions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Freiburg ethics commission international, 28/09/2015, ref: 015/1560

Study design
Multi-centre prospective non-interventional study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Other

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
Angina pectoris

Interventions
Participants with chronic stable angina pectoris who are being treated with IMPLICOR® according to physicians assessment and the Summary of Product Characteristic (recommended dose: twice a day one tablet, one in the morning and one at night) are informed about the study and written consent for participation is obtained. Treatment is observed and data are documented over a period of 4 months. At baseline (U1) physician documents data about anamnesis and treatment with IMPLICOR®. Patient questionnaire regarding compliance is handed out and filled out by patient. About 1 month after baseline (U2), patients attend a further appointment and changes of concomitant medication, information on chronic stable angina pectoris and treatment with IMPLICOR® are documented. If applicable, adverse events and safety information are recorded. A final examination (U3) should take place about four months after baseline. At this appointment changes of concomitant medication, information on chronic stable angina pectoris, treatment with IMPLICOR® and adverse events and safety information are documented. IMPLICOR® therapy is assessed by physician and patient questionnaire regarding compliance is handed out and filled out by patient.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Metoprolol, ivabradine

Primary outcome measure
1. Influence of IMPLICOR® therapy on heart rate at each visit measured at baseline, 1 month and 4 months
2. Influence of IMPLICOR® therapy on number of angina attacks at each visit measured at baseline, 1 month and 4 months

Secondary outcome measures
1. Influence of IMPLICOR® therapy on use of short-acting nitrates measured at baseline, 1 month and 4 months
2. Influence of IMPLICOR® therapy on symptomatic classification (CCS-class) by physicians' assessment measured at baseline and 4 months
3. Influence of IMPLICOR® therapy on hospitalization rate measured at baseline and 4 months
4. Influence of IMPLICOR® therapy on patients’ compliance/adherence measured at baseline and 4 months
5. Adding of knowledge regarding general tolerance and specific adverse drug reactions (ADR) under IMPLICOR® therapy by standardized questionnaire measured at 1 month and 4 months
6. General assessment of IMPLICOR® therapy in symptomatic patients with angina pectoris by physician measured at 4 months

Overall study start date
01/06/2015

Completion date
30/09/2016

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Ambulatory patients with chronic stable angina pectoris, who are treated according to the indication of IMPLICOR®.
3. Patients who were treated with free combination of active substances and who were controlled with equivalent doses of the free combination.
4. Patients with or without concomitant diseases

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1500

Total final enrolment
747

Key exclusion criteria
1. Less than 18 years of age
2. Patients with contraindications to IMPLICOR®

Date of first enrolment
02/11/2015

Date of final enrolment
31/01/2016

Locations

Countries of recruitment
Germany

Study participating centre
Heart Center of the University of Rostock (Herzzentrum der Universität Rostock)
Schillingallee 35
Rostock
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18057

Sponsor information

Organisation
Servier Deutschland GmbH

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Sponsor type

Industry

Website
http://www.servier.de/

ROR
https://ror.org/05wk4ae67

Funder(s)

Funder type
Industry

Funder Name
Servier Deutschland GmbH

Results and Publications

Publication and dissemination plan
Statistical analysis and preparation of an integrated final report takes place after completion of data collection. It is planned to publish the core results of the study.

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Georg Stöckl (georg.stoeckl@servier.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		01/08/2017	16/10/2017	No	No
Results article	results	01/12/2017		Yes	No
Results article	results	01/12/2019	15/08/2019	Yes	No