

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	☒ Prospectively registered ☐ Protocol
Registration date 28/10/2015	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 15/08/2019	Condition category Circulatory System	☐ 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

Contact name

Dr Georg Stöckl

Contact details

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Additional identifiers

Protocol serial number

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

Primary study design

Observational

Study design

Multi-centre prospective non-interventional study

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

Germany

18057

Sponsor information

Organisation

Servier Deutschland GmbH

ROR

<https://ror.org/05wk4ae67>

Funder(s)

Funder type

Industry

Funder Name

Servier Deutschland GmbH

Results and Publications

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