ISRCTN59609019 https://doi.org/10.1186/ISRCTN59609019

Influence of heart rate reduction on heart injury that happens during interventional coronary procedure and stent deployment in patients with coronary disease

Submission date
29/06/2018

Recruitment status
No longer recruiting

Registration date
06/07/2018

Overall study status
Completed

Last Edited
05/08/2021

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
There is no data that heart rate reduction reduces periprocedural myocardial injury in patients undergoing elective percutaneous coronary intervention (angiography of coronary vessels with subsequent stent implantation in narrowed segments in order to reestablish normal blood flow through coronary vessels). Ivabradine is an established drug that reduces heart rate (HR) and subsequently alleviates symptoms of angina (heart pain due to coronary stenoses). In this study we sought to determine whether HR reduction via ivabradine attenuates or reduces the amount of myocardial injury that in small extent occurs during stent implantation.

they were eligible if heart rate was above 70/min and afterwards randomized in two groups (ivabradine group and control group)
40 patients with stable angina and resting heart rate above 70 beats per minute (bpm) were assigned to ivabradine 5 mg twice daily. The control group consisted of 40 patients with resting heart rate above 70 bpm. All patients were included 1 month before scheduled intervention. After admission troponin I levels (blood marker of myocardial damage or injury) were measured before the procedure and after 24 hours. We also collected data of any change in symptoms in both groups.

The benefit was that patients were examined more frequently; also the clinical benefit of treatment with ivabradine was previously proven and the prescription was in line with guidelines for treatment of patients with ischemic heart (coronary) disease. There were no potential additional risks for included patients.

Contact information

Type(s)
Scientific

Contact name

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Additional identifiers

Protocol serial number
2010/5

Study information

Scientific Title
Effect of heart rate reduction on periprocedural myocardial injury and angina symptoms in elective patients with coronary disease undergoing coronary intervention

Study objectives
Heart rate reduction via ivabradine treatment reduces periprocedural myocardial injury and reduces symptoms in patients with stable coronary disease undergoing interventional coronary procedure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional ethics committee University Clinical center Maribor, 05/05/2010, approval Nr: 092-30/2010

Primary study design
Interventional

Study design
Single-center interventional study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Ischemic heart disease with stable angina

Interventions

After inclusion criteria were met patients were invited to participate in study. Informed consent was obtained, and patients were instructed to attend first visit one month before planned procedure. At first visit heart rate was reassessed. Patients were asked about their usual therapy adherence and then instructed to rest for five minutes. 12-lead ECG was recorded and if eligible (heart rate > 70 bpm) patients were then randomly assigned to one of two groups. Patients were randomized so that the first patient was in group 1 and the second was in group 2 and so on. Patients in group 1 were prescribed ivabradine 5 mg twice daily on top of their standard therapy and patients in group 2 received no additional treatment. Treatment with ivabradine wasn't stopped after the study conclusion. There was no long-term follow-up or additional visits for the patients included in the protocol, patients had regular visits based on their clinical characteristics.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Ivabradine

Primary outcome(s)
Periprocedural myocardial injury, measured using cardiac troponin I assay (Siemens Healthcare Diagnostics) from blood samples at admission (before the procedure) and 24 hours after the procedure

Key secondary outcome(s)
Symptoms of angina, assessed with the number of angina attacks (chest pain) per week, on the day of inclusion and 1 month after the inclusion

Completion date
06/04/2016

Eligibility

Key inclusion criteria
1. Patients scheduled for elective PCI
2. Suspected or established coronary artery disease
3. Presence of sinus rhythm
4. Resting heart frequency above 70 beats per minute

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
78

Key exclusion criteria
1. Previous pacemaker implantation
2. Symptoms and signs of heart failure
3. Ejection fraction of left ventricle below 50%
4. Levels of creatinine above upper level of normal (ULN)
5. Already treated with ivabradine

Date of first enrolment
17/05/2010

Date of final enrolment
18/07/2014

Locations

Countries of recruitment
Slovenia

Study participating centre
University clinical center Maribor
Ljubljanska 5
2000 Maribor
Slovenia
2000

Sponsor information

Organisation
University clinical center Maribor

ROR
https://ror.org/02rjj7s91

Funder(s)

Funder type
Industry

Funder Name
Servier

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 Franjo Naji (franjo.naji@yahoo.com) in anonymised form in an Excel table. The decision to share data depends on the type of inquiry and person involved. No special consent of patients to share the data.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Presented at ESC Congress 2014	18/03/2021	05/08/2021	Yes	No
Abstract results		30/08/2014	05/08/2021	No	No