BIO monitoring in patients with preserved left ventricular function after diagnosed acute Myocardial Infarction.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Myocardial disorders
Study type	Interventional

Summary

ID

NL-OMON55877

Source
ToetsingOnline

Brief title
BIO|Guard-MI study

Condition

- Myocardial disorders

Synonym
left ventricular ejection fraction, Myocardial infarction

Research involving
Human

Sponsors and support

Primary sponsor: Biotronik SE & Co.KG

Source(s) of monetary or material Support: BIOTRONIK SE & Co. KG

Intervention

Keyword: Implantantable Cardiac Monitor, left ventricular ejection fraction (LVEF), Myocardial Infarction

Outcome measures

Primary outcome

To investigate wether the early diagnosis of arrythmias with the BioMonitor

system will decrease the risk to experience a Major Adverse Cardiac Event

(MACE). Primary enpdoint: time to first MACE.

Secondary outcome

All cause mortality and all individual components of the composite enpoints

(MACE).

Study description

Background summary

Survivors of AMI who have a severely impaired left ventricular ejection fraction (LVEF) are at high risk of dying suddenly due to cardiac arrhythmias. CARISMA was the first study to use implantable cardiac monitors (ICMs) for continuous ECG monitoring of cardiac arrhythmias in the post-MI setting including patients with LVEF * 40 % and still represents the only experience in this area. This study documented unexpectedly high incidences of new-onset atrial fibrillation (AF), high degree atrioventricular (AV) block, sinus bradycardia, ventricular tachycardia (VT) and ventricular fibrillation (VF). In summary, 46 % of all patients presented with at least one of the pre-specified cardiac arrhythmias of which 85 % were asymptomatic. With a mean follow-up duration of two years, 20 % of patients experienced a major adverse cardiac event (MACE) including death or hospitalization due to heart failure, re-infarction and stroke. More than 80 % of them were diagnosed with an arrhythmia before the event. Hence, a cardiac arrhythmia was the most powerful predictor of a MACE. The study, however, left it open whether preventive treatment based on ICM detections will decrease the incidence of cardiovascular events in high-risk patients. The assessed high incidences and prognostic

significance of cardiac arrhythmias underline the importance of continuous rhythm monitoring in high risk patients after AMI. ICMs provide a much more detailed picture of the incidence of brady- and tachyarrhythmias than conventional follow-up. In addition, newer ICMs (e.g. BioMonitor) include improved
algorithms that allow distinguishing different arrhythmias, and also the diagnosis of normofrequent AF, compared to earlier devices such as those used in the CARISMA study. A unique feature of the BioMonitor is the implemented BIOTRONIK Home Monitoring® function which allows remote access to the subcutaneous electrocardiogram (sECG) recordings. It has been suggested that remote monitoring significantly increases the efficacy of the ICM. The CARISMA study included patients within severly depressed LVEFs * 40 %. However, 80-90 % of patients surviving AMI have a relatively preserved LVEF and are therefore assumed to be at lower risk for MACE and arrhythmias. While this group as a whole may have a relatively benign prognosis, this may not be justified in subgroups with additional cardiovascular risk factors, particularly increasing age, hypertension and diabetes. Moreover, reduced LVEF is less frequent after introduction of percutaneous coronary intervention (PCI) and addition of multiple antithrombotic agents after revascularization. In a recent study including 1500 unselected consecutive patients with AMI most of the premature deaths due to cardiovascular cause occurred in the group of patients with relatively preserved LVEF but with other risk factors. Thus, there is a clinical need to identify patients at high risk for MACE and arrhythmias with preserved or only mildly reduced cardiac function but other cardiovascular risk factors in place. The BIO|GUARD-MI study has been planned to address this need. It was therefore
crucial to implement a tool for risk stratification beyond LVEF to correctly identify patients at high risk after AMI.
Although the CHADS2-score has been designed to estimate the stroke risk in patients with AF, evidence has been provided that the score is highly prognostic as a risk stratification tool for both MACE and arrhythmias in patients with LVEF * 40 % after AMI. In this population the risk of experiencing a MACE was 8 times higher, and the risk of any arrhythmia was 3.7 times increased in patients with CHADS2-score * 3 compared to CHADS2-score = 0. Also in other populations, the CHADS2-score is connected to the risk of AFand bradyarrhythmias. Moreover, the individual components of the CHADS2-score (congestive heart failure, hypertension, age, diabetes, stroke) have also been found to be independently associated with increased risk of VT/VF and are all known to be independent risk factors for worse outcome in patients after AMI.
In recent years, the CHA2DS2-VASc-Score has superseded the CHADS2-score for its original purpose of stroke risk estimation in AF patients due to a better performance especially in patients with a low risk. Both scores are based on the same items, with the CHA2DS2-VASc-Score adding points for age above 75 years, female gender and vascular disease. Although more data are available on the general cardiovascular risk prediction of the older CHADS2-Score, it is justified to assume that the CHA2DS2-VASc-Score will perform similarly well for the purpose of this study. Because the CHADS2-score is perceived as outdated

and inferior by many cardiologists, the CHA2DS2-VASc-Score will be used as main entry criterion of this study.
Compatible with the conclusions drawn from CARISMA, large randomized controlled trials have firmly established that post-MI patients with LVEF * 35% benefit from the implantation of an ICD, which is reflected in current guidelines. However, also patients with a preserved or mildly reduced LVEF (* 35%) but with additional cardiovascular risk factors, such as those expressed within the CHA2DS2-VASc-Score, may be considered at high risk for experiencing both cardiac arrhythmias and consequent MACE. Nevertheless, scientific studies in this population remain sparse. The BIO|GUARD-MI study therefore aims to investigate whether continuous arrhythmia monitoring and detection, using an ICM (BioMonitor) in patients after AMI with LVEF > 35 % but other cardiovascular risk factors, decreases the risk of MACE if patients are appropriately examined and treated for the observed arrhythmias.

Study objective

The objective of the the BIO|GUARD-MI study is to investigate whether the early diagnosis of cardiac arrhythmias, provided by the BioMonitor in connection with remote monitoring, and the consequent treatment of the patient will decrease the risk to experience a MACE in patients with AMI, CHA2DS2-VASc-Score * 4 in men / * 5 in women and LVEF > 35 %.

Study design

Prospective, controlled, randomized, parallelgroup, open, multi-center, international study

Intervention

The BioMonitor group receives an implantable cardiac monitor - the BioMonitor

Study burden and risks

6-montly telephone contact using a quality of life questionnaire (WHO-5), health questionniare (EQ-5D-5L) and questions focused on endpoint related data (e.g. cardiovascular hospitalizations).

For the BioMonitor group there is the risk for complications related to the if invasive implantation procedure. Known risks and complications are: bleeding, swelling or pain at implant wound, infections and/or local tissue reaction, device migration. see protocol paragraph 6

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

History of an acute myocardial infarction
CHA2DS2-VASc-score * 4 in men / * 5 in women
LVEF >35%

Exclusion criteria

Patients with haemorrhagic diathesis,
permanent oral anticoagulation treatment for atrial fibrillation,
pacemaker or ICD implanted or indication for implantation

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-12-2018
Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	BioMonitor
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-05-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	04-07-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	

Date:	21-10-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-05-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT02341534
CCMO	NL63408.100.17