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Post-market clinical follow-up study evaluating the efficacy and safety of the wearable cardioverter-defibrillator (WCD) medical device 'LifeVest' in real-life settings in France

Submission date
04/12/2015

Recruitment status
No longer recruiting

Registration date
29/01/2016

Overall study status
Completed

Last Edited
10/03/2016

Condition category
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
A sudden cardiac arrest (SCA) is a serious medical condition in which the heart suddenly is unable to function normally, without warning. In most cases, this is triggered by an electrical malfunction within the heart muscle affecting the rhythm of the heart beat. When this happens, blood stops flowing to the brain and other vital organs, causing unconsciousness and death within minutes. In order to treat someone experiencing a SCA, an electric shock to the heart is delivered, using a device called a defibrillator, which “re-sets” the heart’s rhythm. Some people, particularly those with a history of heart disease, have a higher risk of having a SCA than the general population. LifeVest is a treatment option for patients at risk of SCA, offering protection and continuous monitoring of their heart. Unlike a typical implanted defibrillator (which is a implanted pacemaker-like device under the skin), LifeVest is a wearable defibrillator (worn outside the body). This is particularly advantageous for those who are unsuitable for an implantable device, those who have had to have their implant removed due to infection and those awaiting a heart transplant. The efficacy and safety of the LifeVest device has been shown in previous studies, but the impact of using LifeVest in clinical routine in France remains unassessed. The aim of this study is to evaluate the efficacy and safety of the LifeVest device in protecting patients from SCA in a clinical routine setting.

Who can participate?
Patients who have been prescribed LifeVest treatment in clinical routine.

What does the study involve?
Participants are asked for permission to use their medical and device data from clinical routine in a study database. The LifeVest device, which is usually worn for between 1 and 6 months, automatically transmits data about their heart rhythm and how the device is working to a central database, which can be accessed by their doctor. Patients who have already used the LifeVest device are also asked for permission for the study team to review their past data on the system and transfer it to the study database. Throughout the study, the effectiveness of the LifeVest

device is analysed by recording the number of potentially life-threatening arrhythmic events and successful shocks the device delivered which have prevented SCA.

What are the possible benefits and risks of participating?
There are no direct risks or benefits to participants taking part in the study because the LifeVest is prescribed in clinical routine and no additional interventions or procedures will happen to participants.

Where is the study run from?
Clinique Pasteur, Toulouse (France)

When is the study starting and how long is it expected to run for?
March 2016 to February 2018

Who is funding the study?
ZOLL (USA)

Who is the main contact?
Ms Sabrina Koschel
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15.10.2015

Study information

Scientific Title
Post-market clinical follow-up study evaluating the efficacy and safety of LifeVest in real-life settings in France

Acronym
PMS LifeVest

Study objectives
The aim of this study is to investigate the efficacy and safety of LifeVest in real-life settings in France.

Ethics approval required
Old ethics approval format

Ethics approval(s)
No specific ethics approval is required in France due to the observational nature of this study (chapter IX of the French Data Protection Act) which requires submission to CCTIRS (the committee which evaluates research methodology under the principles of the Data Protection Act), but not to CCP (ethics committee).

Study design
Post-market observational study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Sudden cardiac death (SCD)

Interventions
Patients qualify for participation by wearing a LifeVest device in clinical routine. Mean WCD wearing time is anticipated to be three months. However, some indications for wearing the WCD may be longer (up to 6 months) or shorter (only one month). For patients who are listed for heart transplantation, the wearing time is scheduled until heart transplantation is performed, or an ICD will be implanted. The WCD (LifeVest) device directly transmits to a central data server in the USA, Pittsburgh, which is compiled in a central database to which the treating physician has access via an internet platform enabling him to review any potential arrhythmic event detected by the device.
Patients who have already completed use of LifeVest before start of the study in the corresponding study site can also be asked to consent for use of their clinical data.

Intervention Type

Primary outcome measure
Success of LifeVest in terminating life-threatening ventricular arrhythmias, measured as the success rate of appropriate shocks. Data of all arrhythmic events will be transferred automatically from the LifeVest device to a central database. An independent Clinical Event Committee will during the study period use these data to adjudicate all arrhythmic events for adequate termination.

Secondary outcome measures
1. Use of LifeVest in patients at high risk for SCD in clinical practice (i.e. indications, duration of prescription, circumstances associated with the prescription)
2. Risk associated with LifeVest use is determined by measuring the amount of inappropriate shocks (one administered while a patient is not experiencing either sustained VT or VF) is assessed at the end of the study period
3. Patient safety while using LifeVest including cardiac and non-cardiac death, hospitalization, heart surgery, arrhythmic events and other cardiac events is measured through the review of patient medical notes at the end of the study period
4. Patient compliance is determined using the history of recorded appropriate WCD use during the wearing of the WCD (LifeVest ®) by the patients physician is assessed at the end of the study period
5. Factors influencing the non-compliance of patients (age, gender, neurologic function, co-morbidities etc.) is determined by the investigator at time of inclusion
6. Circumstances associated with the withdrawal of LifeVest (i.e. ICD implantation, heart transplantation, LVEF improvement) is determined by the investigator at the time of withdrawal
7. Technical malfunctions and misuses related to the device is determinded by the investigator at the end of the wearing period

Overall study start date
01/03/2016

Completion date
28/02/2018

Eligibility

Key inclusion criteria
Patients receiving a LifeVest prescription in clinical routine. The following indications are authority approved:
1. Implantable cardiac defibrillator (ICD) removal due to cardiac device infections
2. A bridge to heart transplantation
3. In the early post-MI period with left ventricular (LV) dysfunction (LVEF <30%)
4. Recent coronary revascularization with LV dysfunction (LVEF < 30%)

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
550

Key exclusion criteria
Patients who are physically or mentally unable to handle and use the WCD device appropriately, as judged by their responsible physician.

Date of first enrolment
01/03/2016

Date of final enrolment
28/02/2018

Locations

Countries of recruitment
France

Study participating centre
Clinique Pasteur Toulouse
45 Avenue de Lombez
Toulouse
France
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Sponsor information

Organisation
ZOLL

Sponsor details
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
ZOLL

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
30/09/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available