

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	☒ Prospectively registered ☐ Protocol
Registration date 29/01/2016	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 10/03/2016	Condition category Circulatory System	☐ 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

Protocol serial number

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

Study type(s)

Prevention

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(s)**

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.

Key secondary outcome(s)

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 determined by the investigator at the end of the wearing period

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

Healthy volunteers allowed

No

Age group

All

Sex

All

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

31076

Sponsor information

Organisation

ZOLL

Funder(s)

Funder type

Industry

Funder Name

ZOLL

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available