Trial Description

Title

Carepace compression system compared to standard postoperative threatment after pacemaker or defibrillator implant

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Subject: prevention of postoperative hematomas in anticoagulated patients after pacemaker or defibrillator implant.
Included are patients in whom an initial implantation or revison of a cardiac pacemaker or defibrillator is planned and who receive anticoagulative therapy (at least platelet aggregation inhibitor or oral anticoagulant).
Basic assumption of this trial:
The CarePace compression system has advantages over the standard postoperative measures . It allows the substantial reduction of postoperative complications, such as clinically significat pocket hematoma, because CarePace improves immobilization , compression and cooling.

Brief Summary in Scientific Language

The occur of pocket hematoma is a common complication after pacemaker or ICD implantation.
The probability of large hematoma is between 2 % and 16 %, depending on patient characteristics and antithrombotic therapy.
Large pocket hematoma often lead to prolonged hospitalization or require reoperation
It may also be necessary to interrupt oral anticoagulation. (1. Wiegand UK, LeJeune D, Boguschewski F, et al. Pocket hematoma after pacemaker or implantable cardioverter defibrillator surgery: influence of patient morbidity, operation strategy, and perioperative antiplatelet/anticoagulation therapy. Chest. Oct 2004; 126(4):1177-1186. 2. Birnie DH. Healey JS, Wells GA, et al. Pacemaker or defibrillator surgery without interruption of anticoagulation. The New England journal of medicine. May 30 2013;368(22):2084-2093. 3. Ozcan KS, Osmonov D, Yildirim E, et al. Hematoma complicating permanent pacemaker implantation: the role of periprocedural antiplatelet or anticoagulant therapy. Journal of caridiology. Aug 2013;62(2):127-130.)To prevent the occurrence of clinically signifcant pocket hematoma , the oral Antikoagulation is adjusted .
Compression bandages , sandbags to local compression , ice for cooling and the postoperative immobilization of the arm are standards here.
The integrated cooling pad of CarePace is now used as an alternative combined cooling and compression bandage available.
The study will determine whether the use of the Carepace Association may reduce

the risk of occurrence of relevant hematomas after pacemaker and defibrillator implantations
For patients who have a higher risk for postoperative bleeding complications the CarePace bandage may be a better solution.

Organizational Data

- DRKS-ID: **DRKS00009808**
- Date of Registration in DRKS: **2016/01/07**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **EA1/264/14 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

Health condition or Problem studied

- ICD10: **T81.0 - Haemorrhage and haematoma complicating a procedure, not elsewhere classified**
- ICD10: **T82.1 - Mechanical complication of cardiac electronic device**

Interventions/Observational Groups

- Arm 1: **1. Control group:**
  Standard post operative management

  a) put on tape with compression underneath that stays until next day
  b) put on sand sack on compression bandage within first 12 to 24 hours after surgery
  c) cooling wound area, change ice bag every 2 hours
  d) patient shouldn’t move to guarantee immobilization of arm
  e) bed rest for 12 hours but not longer
  f) removing bandage after 12 to 24 hours.

- Arm 2: **2. Intervention group:**
  Carepace compression system

  a) put on Carepace within 12-24 hours postoperative
  b) bed rest for 12 hours but not longer
  c) connect internal cooling circuit with generator next to bed
  d) remove bandage after 12 to 24 hours

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Occurrence of clinical relevant hematoma are defined by a hematoma-score:
- size >20x20cm and decrease of hemoglobin >2 points
- palpable mass of hematoma, min. 2 cm
- prolongation of hospital stay
- pocket infection caused by existing hematoma
- reoperation required due to hematoma
- running anticoagulation has to be reduced or paused

The occurrrence of clinical relevant hematoma will be checked on
a) the first postoperative day and
b) between the 11.-15. postoperative day.
c) after 6 weeks final follow-up

Secondary Outcome

Secondary outcome such as displacement of materials, pocket infections and prolonged wound healing will be mesured by their typically clinical appereance the first day postoperative and between the 11.-15. day after surgery.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Medizinische Klinik m. S. Kardiologie, Rhythmologie-Elektrophysiologie und Devicetherapie; Charité Campus Virchow Klinikum, Berlin**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/03/11**
- Target Sample Size: **120**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **90 Years**

Additional Inclusion Criteria

-Planned primary implenation of pacemaker or ICD.
-Therapy with at least one antiplatelet or an oral anticoagulant -
-Age over 18 years
-Capacity to consent
-Existence of a written informed consent form

Exclusion criteria

-Clear idication for one of the possible prodcedere
-Pregnancy
-Legally in medical matters supervised patients
-Participation in another interventional study

Addresses

- **Primary Sponsor**

  Medizinische Klinik m. S. Kardiologie Rhythmologie-Elektrophysiologie und Devicetherapie; Charité Campus Virchow Klinikum
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- **Contact for Scientific Queries**

Contact for Scientific Queries

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Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

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URL: **[---]***

Status

■ Recruitment Status: **Recruiting ongoing**

■ Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*