UNIVERSITAS INDONESIA

Efficacy of Sternum Guard™ in comparison of Bone Wax in Post Cardiac Surgery Patient: A Single Blind, Single Centre, Randomized Control Trial

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RESEARCH SUBJECT INFORMED CONSENT

I, Dr. dr. Dudy Arman Hanafy, Sp. BTKV (K) MARS and research team (dr. Konda Kinanti Muroso) which is led by Dr. dr. Dudy Arman Hanafy, Sp. BTKV (K) MARS from Adult Cardiac Surgery Division, RS Jantung dan Pembuluh Darah Harapan Kita, Jakarta, will conduct research with a title of The Efficacy of Sternum Guard™ in comparison of Bone Wax in Post Cardiac Surgery Patient: A single blind, single centre, randomized control trial.

This study aims to get an overview of the effectiveness of the Sternum Guard to reduce the incidence of surgical wound infections in the sternum area in patients who have completed heart surgery at PJNHK.

The research team invited Mr/ Mrs. to participate in this study.

The study required about 414 study subjects, with a period of participation of each subject of about 4 weeks (1 month).

A. Volunteering to participate in research

You are free to choose participation in this study without any compulsion. If you have decided to join, you are also free to resign/ change your mind at any time without any fine or sanctions.

If you are not willing to participate then you will still get the same service without being distinguished.

B. Research Procedure

If you are willing to participate in this research, you are required to sign this two-copy consent, one for you to keep, and one for the researcher. The next procedure is:

1. You will be interviewed by a doctor to ask: Name, age, history of disease, history of drug use, history of allergies, smoking habits, drinking habits or drinking beverages containing alcohol.
2. Undergo a physical examination by a doctor to check your health status
3. The basic pre-surgical examinations recorded are; anamnesis, physical examination, plain thoracic photographs, electrocardiography, echocardiography, coronary and laboratory angiography; Complete peripheral blood (DPL), hemostasis function, heart enzymes, liver function, kidney function, blood glucose, as well as blood gas analysis (AGD).
4. Preoperative preparation will be carried out in accordance with the standards of Our Hope Hospital (fasting, etc.)
5. Once in the operating room, anesthesia will be given.
6. Then you will have heart surgery using a heart bypass machine - lung and according to the type of surgery and according to standard procedures.
7. When the operation will be performed the median sternotomy procedure (the bone in the middle of the chest will be separated using an electric saw), then the procedure will be performed to overcome bleeding from the sternum then the patient who belongs to the Sternum Guard group will be installed Sternum Guard during the operation. For patients in the Bone Wax group, after bleeding from the bone can be sufficiently resolved, the bone will be given Bone Wax and sterile gauze installation during surgery.
8. Post-surgery, in the ICU continued data retrieval. Conducted monitoring of clinical, hemodynamic, drain production, plain thoracic photos, electrocardiography, echocardiography, laboratory; Complete

peripheral blood (DPL), hemostasis function, heart enzymes, liver function, kidney function, blood glucose, as well as blood gas analysis (AGD). The blood taken is approximately 5 - 10 cc.

9. Surgical wound infection assessment by taking photo documentation (without face) in the chest area on the 0th day post-surgery, the last day of hospital treatment, the 14th day postoperative (while in poly), the 30th day post-surgery (while in poly).
9. Each study subject was followed until discharge from the hospital. Then post-surgical clinical variables will be complemented. Data is collected by a single data collector, so data reliability is guaranteed.

C. Liability of the research subject

As a research subject, Mr. /Mrs. is obliged to follow the rules or research instructions as written above. If something is not clear, you can ask further questions to the researcher. During the study, it was not permissible to take other drugs or herbs other than those given by researchers or a team of heart doctors from PJNHK.

D. Risks and Side Effects and Management

The risk that this study can occur is surgical wound infection. During the study, researchers prepared the necessary protection in case something unwanted happened. The protection provided by researchers is anti-inflammatory for allergies, antibiotics for bacterial infections, modern wound dressings for surgical wound infections.

E. Benefit

The direct advantage you get is that you get a laboratory examination about hematology, inflammation of the body, liver function, kidney function, and heart function for free. In addition, subjects have the opportunity to be part of the development of science, especially in heart surgery.

F. Confidentiality

All information relating to the identity of the study subject will be kept confidential and will only be known to researchers and research staff. The results of the study will be published without the identity of the study subjects.

G. Compensation

Mr./ Mrs. will get laboratory examinations to find out the condition of the blood, the condition of inflammation of the body, liver function, kidney function and heart function for free. Compensation in the form of material was not provided in this study.

H. Cost

All research-related costs will be covered by the sponsor.

I. Additional information

Mr. / Mrs. is given the opportunity to ask all the things that are not yet clear in this study. If at any time, there are side effects or require further explanation, you can contact us, Dr. dr. Dudy A. Hanafy, Sp. BTKV (K) MARS and research team at 085813775000 or Adult Cardiac Surgery Division or Adult Cardiac Surgery Policlinic, RS Jantung dan Pembuluh Darah Harapan Kita.

You can also ask about research to Ethical Committee, RS. Jantung dan Pembuluh Darah Harapan Kita, Phone. 5681111, ext. 2837/2831 or email: irb.kometik_rsjpdhk@gmail.com.

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All these explanations have been presented to me and all my questions have been answered by the researcher/doctor. I understand that if I need an explanation, I can ask the research team. (dr. Konda Kinanti Muroso)

By signing this form, I agreed to participate in this research.

Signature: **Date:**

(**Full name** :.....)

Witness' signature:

(**Full name** :.....)