TOPICAL APPLICATION EFFECT OF TRANEXAMIC ACID IN POSTOPERATIVE BLEEDING AND BLOOD PRODUCTS TRANSFUSION AFTER CARDIAC SURGERY

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RESEARCH SUBJECT INFORMED CONSENT

I, Dr. dr. Dudy Arman Hanafy, SpBTKV(K), MARS / Research Team (Dr. dr. Dudy Arman Hanafy, Sp.BTKV(K)-D, MARS, dr. Sugisman, Sp.BTKV(K)-D, dr. Rendy Agustian, dr. Putu Lokita Pradnyana Putra, dr. Bastian Simorangkir from the Division of Adult Cardiac Surgery, Harapan Kita Heart and Vascular Hospital, Jakarta will conduct a study entitled **Topical Application Effect Of Tranexamic Acid In Postoperative Bleeding And Blood Products Transfusion After Cardiac Surgery.**

This study aims to determine the amount of postoperative bleeding and the need for blood transfusion in patients undergoing adult cardiac surgery with topical tranexamic acid application compared with placebo.

The research team invites you to participate in this study.

The study required about 132 research subjects, with each subject's participation period of about 5-7 days.

A. Volunteering to participate in research

You are free to choose to participate in this study without any coercion. If you have decided to participate, you are also free to withdraw/change your mind at any time without any fines or penalties.

If you are not willing to participate, then you will still get the same service without any differentiation.

B. Research Procedure

If you are willing to participate in this study, you are asked to sign this consent form in duplicate, one for you to keep, and one for the researcher. The next procedure is:

1. You will be interviewed by the doctor to ask: Name, age, medical history, medication history, allergy history, smoking habits, drinking habits or alcohol-containing beverages.
2. Undergoing a physical examination by a doctor to check the health status.
3. The basic pre-surgical examinations recorded were history taking, physical examination, thoracic plain photographs, electrocardiography, echocardiography, coronary angiography and laboratory; complete peripheral blood (DPL), CRP, procalcitonin, hemostasis

function, cardiac enzymes, liver function, renal function, blood glucose, and blood gas analysis (AGD).

4. Preoperative preparation will be done according to Harapan Kita Hospital standard (fasting, etc).
5. At the time of surgery in accordance with standard operating procedures, you will be given the intervention of getting 5 grams of tranexamic acid dissolved in 50 mL of 0.9% NaCl and subjects in the placebo group getting 100 mL of 0.9% NaCl. Both are administered intrapericardially before sternotomy closure in cardiac surgery.
7. Postoperative, further data was collected in the ICU. Monitoring of the amount of bleeding as seen from the accumulated volume of fluid collected in the WSD bottle and the need for blood component units required by the subject for transfusion was carried out.
9. Each study subject is followed until moving to the usual care room. Then post-surgical clinical variables will be completed. Data was collected by a single data collector, so data reliability was assured.

C. Liability of the research subject

As research subjects, you are obliged to follow the research rules or instructions as written above. If something is not clear, you can ask the researcher further. During the study, it is not allowed to take other drugs or herbs other than those given by the researcher.

D. Risks and Side Effects and Management

The drug tranexamic acid has so far been widely used and does not give significant side effects but sometimes some people can get drug allergies.

During the study, the researcher prepared the necessary protection in case something untoward happened. The protection provided by the researcher is anti-inflammatory for drug allergies.

E. Benefit

The immediate benefit is that you get laboratory tests to determine the state of your blood, liver function, kidney function and heart function free of charge. In addition, the subject could be part of the development of science, especially in cardiac surgery.

F. Confidentiality

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

G. Compensation

You will receive laboratory tests to determine the state of blood, liver function, kidney function and heart function free of charge. Material compensation is not provided in this study.

H. Financing

All costs related to the research will be borne by the researcher.

I. Additional Information

You are given the opportunity to ask about all things that are not clear in connection with this study. If at any time side effects occur or need further explanation, you can contact the researchers Dr. dr. Dudy Arman Hanafy, SpBTKV(K)-D, MARS, dr. Sugisman, Sp.BTKV(K)-D, dr. Rendy Agustian, dr. Putu Lokita Pradnyana Putra, dr. Bastian Simorangkir and other research teams at cell phone number 081320466393 / 081338727162 at the Adult Cardiac Surgery Division of Harapan Kita Heart and Vascular Hospital. or through the Adult Cardiac Surgery Polyclinic of Harapan Kita Heart and Vascular Hospital.

You can also inquire about the research with the Research Ethics Committee of Harapan Kita Heart and Vascular Hospital, Tel. 5681111, ext. 2837/2831 or email: irb.kometik_rsjpdhk@gmail.com.

RESEARCH SUBJECT INFORMED CONSENT

All these explanations have been given 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 researcher (Dr. dr. Dudy Arman Hanafy, SpBTKV(K)-D, MARS / dr. Rendy Agustian/ dr. Putu Lokita Pradnyana Putra / dr. Bastian Simorangkir).

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

Subject Signature : **Date:**

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

Witness Signature:

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