Efficacy of Tranexamic Acid in preventing post operative blood loss and associated complications in bone sarcoma patients treated with limb salvage surgery: A randomized controlled trial.

IRB# IRB-22-07

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Efficacy of Tranexamic Acid (TXA) in preventing post operative blood loss and associated complications in bone sarcoma patients treated with limb salvage surgery

You are asked to participate in a research study conducted by Dr. Muhammad Bilal, under supervision of Dr. Ilyas Rafi from the Surgical Oncology Department at Shaukat Khanum Memorial Cancer Hospital and Research Center SKMCH & RC. The Institutional Review Board (IRB) of SKMCH & RC has reviewed this project. IRB is an independent hospital committee that safeguards the welfare and rights of human research participants. Your participation in this study is entirely voluntary. Please read the information below and ask questions about anything you do not understand, before deciding whether or not to participate.

- **INFORMATION ON THE RESEARCH**

1. Why Are You Being Asked To Take Part In This Research?

You have been diagnosed with bone sarcoma and will be undergoing limb salvage procedure. All patients undergoing such procedures are invited for participation in this research.

2. Why Is This Study Being Done?

Limb salvage surgery for malignant bone tumors results in extensive bone and soft tissue resection which leads to massive bleeding and requiring a large number of transfusions. Blood transfusions have complication and sometime can lead to mortality. Blood loss and related complications may lead to high risk of reoperation, an increased hospital stay. Tranexamic Acid is a drug which can decrease perioperative blood loss & blood transfusion related complications. The purpose of this study to assess the effect of tranexamic acid in limb salvage surgery.

3. How Many People Will Take Part In The Study?

This study will include a total of 36 patients who will be randomly divided into two groups of 18 patients each. This randomization will be carried out by an online modality so there is no bias in our recruitment.

4. What Is Involved In The Study?

You will randomly be put into one of the two groups after giving written informed consent for participation in this research study. One will recieve tranexamic acid during the operation while the other will be injected 10 ml of normal saline. As part of our research protocol, you will not know which group you are alloted to only one of research team member will be informed . You will be routinely taken to the Operation Room on the day of your surgery. You will undergo your surgery under general anesthesia during which you will be given an intravenous infusion tranexamic acid if you are assigned to that group or else you would be receiving 10 ml saline as part of the other group. You will undergo the procedure described by your surgeon.

Total blood loss during surgery will be calculated which will need your pre operative hemoglobin, hemoglobin after 72 hour and number of blood transfused to you during these days. Your drain out put will also monitored & recorded

5. How Long Will You Be In The Study?

The length of your participation in this study will start from the time of your surgery until 72 hours after your surgery. After which you will need to visit clinic at 2 week, 4 week and 6 week post-operatively. Patient who will not attend physical clinic will be excluded from the study.

In case we need any additional information or follow up subsequently, you will be informed through hospital telephonic services.

- **POTENTIAL RISKS AND DISCOMFORTS**

Minor side effects with use of tranexamic acid are headache & dizziness in less than 2 % of population. Use of TXA can cause clot formation in limb vessels in less than 1 % of population which can impaired lung circulation if become dislodged. so, you will be monitored for occurrence of side effects of the study drug and managed accordingly**.**
Patients will be given anti-coagulants as per defined protocol for 04 weeks post operatively and will be followed at 4 and 6 weeks in clinics as per routine practice.
Participants on placebo arm are at higher risk of blood loss, increased number of transfusion and prolonged hospital stay. Risks associated with placebo arm are the same as of routine procedure.

- **POTENTIAL BENEFITS TO SUBJECTS AND/OR TO SOCIETY**

The study involves two groups, one receiving TXA and the other normal saline. Patients receiving TXA might get benefits like decrease blood loss, less number of transfusion, short hospital stay and quick recovery as compared to placebo group. This study will help in determining role of tranexamic acid in Limb salvage surgery & will decrease need of blood products which will be cost effective

- **ALTERNATIVES TO PARTICIPATION**

If you do not want to participate in this study, you will not be enrolled in it. There will be no change in your health care or surgical plan which is previously discussed with you by your surgeon and anesthesiologist.

- **CONFIDENTIALITY**

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. All the collected data will be stored in locker cabinet which will be accessible only by the investigators. After retrieving data into SPSS, all the data will be submitted to the hospital Clinical Research Office. Your identity will not be furnished at any point to third party. You will not be Audio or Videotaped.

- **PAYMENT FOR PARTICIPATION**

Your will not receive any payments or allowances for participation in this study. This will be a completely voluntary participation.

- **COMPENSATION/MEDICAL TREATMENT IN CASE OF INJURY**

Any adverse event occurring due to research will be managed as per hospital policy.

- **PARTICIPATION AND WITHDRAWAL**

You can choose whether you wish to be a part of this study. If you volunteer to be in this study, you may withdraw at any time. You may also refuse to answer any questions you do not want to answer. There is no penalty if you withdraw from the study and you will not lose any benefits to which you are otherwise entitled. We will inform you about any new information that may affect your health, welfare, or willingness to stay in this study. The investigator can terminate your participation in this study if your surgical plan changes for any reason

- **IDENTIFICATION OF INVESTIGATORS**

  - Dr. Muhammad Bilal (Principal investigator)

Fellow Doctor in Department of Surgical Oncology, SKMCH&RC
Telephone no: (+92) 333 3286687
E-mail: bilalshafiq@skm.org.pk

  - Dr. Ilyas Rafi (Supervisor)

Consultant Orthopedic t in Department of Surgical Oncology, SKMCH&RC
E-mail**:** ilyasrafi@skm.org.pk

RIGHTS OF RESEARCH SUBJECTS

The Institutional Review Board of SKMCH & RC has reviewed this project. If you have any concerns or questions about your rights in this study as a research subject, you should contact the Secretary, Institutional Review Board at +92-42-35905000 Ext 4280 or mail at crc3@skm.org.pk

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I understand the procedures described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

❖ **Name of Subject** _____ MR No. _____

Signature of Subject Date _____

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❖ **Name of witness** _____ Date _____
(Applicable in case participant is unable to read)

Signature of witness

_____

❖ **Name of interpreter** _____ Date _____
(Applicable in case of language barrier)

Signature of interpreter

_____

❖ **Name of person obtaining consent** _____ Date _____

Signature & Employee code of person obtaining consent

_____

Note: Routing of copies of the consent form:

1. One copy to be given to patient/family;
2. One to be kept in investigator's file/Research record
3. One to be placed in patient's Medical Record