Postoperative bleeding prevention in massive bone tumour resection: A multicentric, randomized, parallel, controlled trial to assess the efficacy of tranexamic acid versus evicel and usual haemostasis [protocol].

Authors: Ibanez A.P., Martinez Zapata M.J., Tarrago L.T., Balaguer M.B., Roig X.A., Joy I.G., Areizaga L., Merino J., Alcala R.

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Abstract:

Objective: To determine whether the use of topical tranexamic acid (TXA) or fibrin glue will reduce perioperative bleeding compared with usual hemostasis in massive bone tumor. Method: Design: Multicentre, randomized, open label, parallel, controlled trial. Setting: Three hospitals. Inclusion criteria: adults, both genders, who consent to participate in the project, with deep >5 cm soft tissue sarcoma or osseous tumor (primary or metastatic, benign or malignant) located in extremities, shoulder girdle, or pelvis that need massive or en bloc tumor resection. Exclusion criteria:low grade liposarcomas, known allergy to TXA o fibrin glue, history of thromboembolic disease, or prothrombotic conditions. Interventions:Group 1: 5 mL fibrin glue plus usual hemostasis; Group 2: 1 g-TXA plus usual hemostasis; and Group 3: usual hemostasis; all administered before closure of the wound surgery. Primary outcome: Total blood loss in the first postoperative 48 h collected by wound drainage system. Secondary outcomes:Proportion of patients requiring blood transfusion, units of blood transfused, proportion of patients with wound complications, deep venous thrombosis, postoperative pain, tumoral relapse rate, proportion of patients in which chemotherapy or radiotherapy was delayed due to wound complications, length of hospital stay, and mortality. Simple size:Accepting an alpha risk of 0.05 and a beta risk of 0.2 in a two-sided test, 145 subjects in total are needed, 45 in each group, to recognize as statistically significant a difference greater than or

equal to 250 mL in blood loss. The common standard deviation is assumed to be 400. It has been anticipated a drop-out rate of 10%. Statistical analysis: We will perform a comparison between groups through the 't' test, the Mann-Whitney test, or the chi square test, depending on whether the assessed outcomes are quantitative' ordinal, or qualitative, respectively. The software used will be SPSS22. Results: The study is ongoing. Conclusions: The study is ongoing.