Determination of the efficacy of EVICELTM on blood loss in orthopaedic surgery after total knee replacement: study protocol for a randomised controlled trial.

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Abstract:

BACKGROUND: After total knee replacement, overall blood loss is often underestimated, although it exceeds the visible blood loss caused by bleeding into the tissues or into the joint. The use of fibrin sealants during surgery has been suggested to reduce perioperative blood loss and transfusion rates and may be beneficial for patient recovery and the postoperative function of the joint.

METHODS/DESIGN: This will be a single-centre, single-blinded, randomised controlled trial with a parallel design, for which 68 patients undergoing total knee replacement will be recruited and followed up at 3, 6 and 12 months; 34 will be control patients who will receive the standard orthopaedic surgery treatment (electrocoagulation), and the other 34 will receive the same treatment plus 5 ml EVICELTM applied during surgery and used according to the manufacturer's instructions. The primary objective is to test the null hypothesis that the effect of EVICELTM for controlling haemostasis and reducing postoperative blood loss in patients undergoing total knee replacement is not superior to the use of electrocoagulation alone. The secondary objective is to show that EVICELTM reduces the need for transfusion, increases range of motion, improves clinical outcome and wound healing, and reduces the need for analgesics. The tertiary objective is to show that EVICELTM reduces the costs of total knee replacement treatment.

DISCUSSION: So far, studies on the effect of fibrin sealants in total knee replacement have

delivered inconsistent and ambivalent results, indicating that there is still a need for high-evidence studies as proposed in the presented study protocol.

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