Comparison of the collagen haemostat Sangustop versus a carrier-bound fibrin sealant during liver resection; ESSCALIVER-Study.

Authors: Moench C, Bechstein WO, Hermanutz V, Hoexter G, Knaebel HP

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Abstract:

BACKGROUND: Haemostasis in liver surgery remains a challenge despite improved resection techniques. Oozing from blood vessels too small to be ligated necessitate a treatment with haemostats in order to prevent complications attributed to bleeding. There is good evidence from randomised trials for the efficacy of fibrin sealants, on their own or in combination with a carrier material. A new haemostatic device is Sangustop. It is a collagen based material without any coagulation factors. Pre-clinical data for Sangustop showed superior haemostatic effect. This present study aims to show that in the clinical situation Sangustop is not inferior to a carrier-bound fibrin sealant (Tachosil) as a haemostatic treatment in hepatic resection.

METHODS/DESIGN: This is a multi-centre, patient-blinded, intra-operatively randomised controlled trial. A total of 126 patients planned for an elective liver resection will be enrolled in eight surgical centres. The primary objective of this study is to show the non-inferiority of Sangustop versus a carrier-bound fibrin sealant (Tachosil) in achieving haemostasis after hepatic resection. The surgical intervention is standardised with regard to devices and techniques used for resection and primary haemostasis. Patients will be followed-up for three months for complications and adverse events.

DISCUSSION: This randomised controlled trial (ESSCALIVER) aims to compare the new collagen haemostat Sangustop with a carrier-bound fibrin sealant which can be seen as a "gold standard" in

hepatic and other visceral organ surgery. If non-inferiority is shown other criteria than the haemostatic efficacy (e.g. costs, adverse events rate) may be considered for the choice of the most appropriate treatment.

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