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Titel des Beitrags: Postoperative negative-pressure incision therapy following open colorectal surgery (Poniy): study protocol for a randomized controlled trial.

Abstract: Postoperative surgical site infections cause substantial morbidity, prolonged hospitalization, costs and even mortality, and remain one of the most frequent surgical complications. In prospective trials with adequate follow-up, more than 20 % of patients undergoing elective colorectal surgery are affected and methods to reduce surgical site infections are urgently needed. Negative-pressure incision therapy is a novel intervention that holds promise to reduce postoperative wound infection rates, but has not yet been rigorously tested in a randomized controlled trial. The aim is to investigate whether the postoperative application of a negative-pressure incision therapy device for 5-7 days reduces the rate of surgical site infections following open elective colorectal surgery by 50 %. This is a randomized, controlled, observer-blinded multicentre clinical trial with two parallel study groups. The primary outcome measure will be the rate of surgical site infections within 30 days postoperatively. Surgical site infections are defined according to criteria of the US Centers for Disease Control and Prevention. Statistical analysis of the primary endpoint measure will be based on the intention-to-treat population. The global level of significance is set at 5 % (two-sided) and the sample size (n = 170 per group) is determined to assure a power of 80 %. The Poniy
trial will explore whether the rate of surgical site infections can be reduced by the application of a negative-pressure incision therapy device in patients undergoing open elective colorectal surgery. Its pragmatic design guarantees high external validity and clinical relevance. Deutsches Register Klinischer Studien DRKS00006199.