ABSTRACT: Postoperative surgical site infections cause substantial morbidity, prolonged hospitalization, costs and even mortality and remain one of the most frequent surgical complications. Approximately 14% to 30% of all patients undergoing elective open abdominal surgery are affected and methods to reduce surgical site infection rates warrant further investigation and evaluation in randomized controlled trials. To investigate whether the application of a circular plastic wound protector reduces the rate of surgical site infections in general and visceral surgical patients that undergo midline or transverse laparotomy by 50%. BaFO is a randomized, controlled, patient-blinded and observer-blinded multicenter clinical trial with two parallel surgical groups. The primary outcome measure will be the rate of surgical site infections within 45 days postoperative assessed according to the definition of the Center for Disease Control. Statistical analysis of the primary endpoint will be based on the intention-to-treat population. The global level of significance is set at 5% (2 sided) and sample size (n = 258 per group) is determined to assure a power of 80% with a planned interim analysis for the primary endpoint after the inclusion of 340 patients.
BaFO trial will explore if the rate of surgical site infections can be reduced by a single, simple, inexpensive intervention in patients undergoing open elective abdominal surgery. Its pragmatic design guarantees high external validity and clinical relevance. http://www.clinicaltrials.gov NCT01181206. Date of registration: 11 August 2010; date of first patient randomized: 8 September 2010.