Summary PROUD Trial

PRINCIPAL INVESTIGATOR	**Markus W. Büchler** MD, Professor and Chairman, Dept. of General, Visceral and Transplantation Surgery, University of Heidelberg
TITLE OF STUDY	**Pr**evention of abdominal w**ou**n**d** infection – **PROUD-Trial**
CONDITION	Patients scheduled for elective open surgery of the abdominal cavity for any reason.
OBJECTIVE(S)	To evaluate possible differences in the frequency of wound infections and wound dehiscence within one month after index operation using two different suture materials for continuous abdominal fascial closure after midline laparotomy.
INTERVENTION(S)	Group 1: Continuous mass closure with an absorbable monofilament loop suture (Polydioxanon) coated with triclosan (PDS II plus). Group 2: Continuous mass closure with an absorbable monofilament loop suture (Polydioxanon, PDS II). Duration of intervention per patient: 20 (15-30) min
KEY INCLUSION AND EXCLUSION CRITERIA	Key inclusion criteria: • Elective midline laparotomy • Age equal or greater than 18 years • Written informed consent Key exclusion criteria: • Impaired mental state or language problems • Participation in another intervention trial with interference of intervention and outcome of this study
OUTCOME(S)	Primary efficacy endpoint: Rate of wound infections (deep and superficial according to CDC) within 1 month after index operation Key secondary endpoint(s): • Frequency of wound dehiscence with or without evisceration • Postoperative hospital stay • 30 day mortality • Quality of life (QoL) Assessment of safety: Rates of serious adverse events (mortality, re-operation, etc.) will be monitored.
DURATION OF TREATMENT AND FOLLOW-UP	Duration of treatment per patient: Will vary according to underlying indication for laparotomy. Follow-up per patient: 1 month
STUDY TYPE	Randomized, controlled, double-blind multi-centre surgical trial with two parallel study groups.

STATISTICAL ANALYSIS	Efficacy: The primary efficacy parameter is the frequency of wound infections within one month after index operation, compared between the two intervention groups applying different suture materials. Description of the primary efficacy analysis and population: The primary efficacy analysis will be conducted in the intention to treat population via binary logistic regression analysis. The level of significance is set at 0.025 (one-sided). Safety: Exploratory analyses of frequencies of serious adverse events. Secondary endpoints: Exploratory analyses.
SAMPLE SIZE	To be allocated to trial: n =1200; may be changed based on the results of the adaptive interim analysis
TRIAL DURATION	First patient in: April 2010 Multicenter design: first patient in : January 2011 First Interim-Analysis: July 2011 Second Interim-Analysis: after 1200 patients
PARTICIPATING CENTRES	N=23