Does caffeine reduce postoperative bowel paralysis after elective laparoscopic colectomy? (CaCo trial): study protocol for a randomized controlled trial

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BACKGROUND
Postoperative bowel paralysis is common after abdominal operations, including colectomy. As a result, hospitalization may be prolonged, thereby leading to increased cost. A recent randomized controlled trial showed that the consumption of regular black coffee after colectomy is associated with a significantly faster resumption of intestinal motility. The mechanism by which coffee stimulates intestinal motility is unknown, but caffeine seems to be the most likely stimulating agent. Thus, the effect of caffeine on postoperative bowel activity after colon surgery will be analyzed in this trial, herein referred to as CaCo.

METHODS/DESIGN
Patients scheduled for elective laparoscopic colectomy or upper rectum resection are eligible to participate in this double-blinded, placebo-controlled, randomized trial. Patients fulfilling all inclusion criteria will be allocated after the surgical procedure to one of three treatment arms: 100 mg caffeine, 200 mg caffeine, or placebo (corn starch). Patients will take the capsules containing the study medication three times daily with a meal. The primary endpoint of the study is the time to a solid bowel movement. The study treatment will be stopped after the patient produces a solid bowel movement or has taken ten capsules, whichever occurs first. To determine the colonic passage time, patients will take a capsule with radiopaque markers at breakfast for the first 3 days after surgery. On the fourth day, the location of the markers will be determined with an abdominal X-ray scan. Further secondary objectives are the postoperative morbidity and mortality, well-being, sleeping behavior, and length of hospital stay. The study size was calculated to be 180 patients with an interim analysis occurring after 60 patients.

DISCUSSION
From a previous study investigating coffee, evidence exists that caffeine might have a positive influence on the postoperative bowel activity. This double-blinded, placebo-controlled, randomized trial tries to show that caffeine will shorten the postoperative bowel paralysis and, thus, will improve recovery and
shorten the hospital stay after colon surgery.

TRIAL REGISTRATION
Clinicaltrials.gov NCT02510911 Swiss National Clinical Trials Portal
SNCTP000001131.

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project CaCo: Does caffeine intake reduce postoperative bowel paralysis after elective laparoscopic colectomy? - A randomized placebo controlled trial

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