



## STUDY SUMMARY

**Title:** An international, cluster randomised-sequence study of a 'Safe-anastomosis' Quality Improvement Intervention to reduce anastomotic leak following right colectomy and ileocaecal resection.

**Background:** Anastomotic leak is a severe, potentially life-threatening complication following right colectomy. Internationally, anastomotic leak occurs after 8% of right colectomies. Prospective cohort data demonstrate that patient selection, intraoperative factors, and technical variation are risk factors for anastomotic leak.

**Aim:** To assess whether implementation of the European Society of Coloproctology (ESCP) Safe-anastomosis Intervention reduces risk of anastomotic leak up to 30-days following right colectomy.

**Design:** International, multi-centre, cluster randomised-sequence service improvement study, with the hospital as the cluster. Phased Dog-leg schedule for repeated assessments with 3 randomisation sequences. Meta-analysis of results will be performed from individual dog legs (indicatively four dog legs).

**Eligibility:** Any hospital or surgical unit performing elective and/or emergency colorectal surgery. Adults (age 16 years and above) undergoing right colectomy or ileocaecal resection for any indication are eligible, including elective, expedited or emergency surgery by open, laparoscopic or robotic approaches.

**Intervention:** Three-component, behavioural change intervention for surgeons, anaesthetists and operating theatre staff, supported by an online learning environment: (1) Pre-operative stratification of patients for risk of anastomotic leak; (2) Harmonisation of technique for formation and assessment of stapled and handsewn ileocolic anastomoses; (3) Implementation of a Safe-anastomosis checklist, completed in-theatre immediately prior to formation of an anastomosis and/or maturation of an ileostomy. All centres will receive the intervention.

**Primary Outcome measure:** 30-day overall anastomotic leak rate, defined as clinical or radiologically detected anastomotic leak or intra-abdominal or pelvic collection.

**Sample size:** To show a reduction from 8.1% to 5.6% (relative risk reduction 30%) we will require 4,400 patients from 333 centres (sites).