ISRCTN79285407 https://doi.org/10.1186/ISRCTN79285407

# Absolok® pilot clinical trial

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| **Submission date**<br>05/02/2026 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[X] Protocol |
| **Registration date**<br>05/02/2026 | **Overall study status**<br>Completed | [X] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>05/02/2026 | **Condition category**<br>Surgery | [_] Individual participant data<br>[X] Record updated in last year |

## Plain English summary of protocol

Background and study aims
Perioperative bleeding currently represents one of the most fearful complications in colorectal surgery, with a reported incidence rate ranging between 1% and 14%. The onset of perioperative bleeding may potentially lead to additional related adverse events, such as postoperative ileus, anastomotic leakage, and sepsis. This inevitably reflects in a prolonged length of hospital stay and higher costs for hospitalization.

In this context, surgeons' ability and the use of adequate hemostatic devices are fundamental to reduce the incidence rate of perioperative bleeding. In this regard, metallic clips are currently recognized as the most used devices for an appropriate ligation of vessels. However, episodes of clip migration and infection nidus formation have been reported in the literature. This has led to the more recent introduction of no-metallic clips, as a valuable alternative to the metallic ones. Among them, the Hem-o-lok and Absolok clips are recognized as the most frequently employed. Hem-o-lok clips are composed of non-absorbable polymers, while the Absolok ones are characterized by bioabsorbable polymers.

Currently no comparative study is present in the literature between the Absolok and Hem-o-lok clips in terms of perioperative bleeding in colorectal surgery. This study aims to compare the hemostatic capability of these two devices in colorectal surgery.

Who can participate?
Adult patients undergoing curative colorectal resection for benign and malignant disease, including right and left hemicolectomies and rectal resections.

What does the study involve?
This study is a small, earlystage clinical trial carried out at a single hospital. It compares two types of surgical clips—Absolok® and HemoLok®—which may be used to close tissues during colorectal operations such as right or left hemicolectomies and rectal resections. Patient enrollment will take place at the Hospital Isola Tiberina – Gemelli Isola and will be based on the following inclusion and exclusion criteria.

All patients scheduled for these types of bowel surgery are eligible to take part, regardless of whether their operation is performed through an open incision, keyhole (laparoscopic) surgery, or with robotic assistance. The surgical procedure follows the standard steps for each operation,

with the only difference being the type of clip used. Participants are assigned at random, using a computer program, to receive one of the two clip types. The purpose of the study is to assess whether both clips can be used safely and effectively in these procedures.

What are the possible benefits and risks of participating?
Benefits not provided at time of registration

Risk analysis, possible problems and solutions
Since the surgical treatment will respect the International Guidelines, no additional risks are expected.

Safety/Adverse Event Management
All adverse events observed during the study will be collected and recorded.
Adverse events involving medical devices can be classified as incidents and deficiency, the aforementioned, as identified by the following definitions, will be reported to the National Competent Authority and to the Manufacturer according to the provisions of current legislation for medical devices (EU Regulation 745/ 2017 and Legislative Decree 5 August 2022, n.137 and subsequent communications from the Ministry of Health).
In the case of a medical device, it means for
• any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons, in the context of a clinical investigation, whether or not related to the investigational device.;
• any inadequacy in the identity, quality, durability, reliability, safety or performance of an investigational device, including malfunction, use errors or inadequacy in information supplied by the manufacturer;
• any incident, malfunction or alteration of the characteristics or performance of a device made available on the market, including the error of use caused by the ergonomic characteristics, as well as any inadequacy in the information provided by the manufacturer and any unwanted side effects.
A serious incident is defined as any incident which, directly or indirectly, has caused, may have caused or may cause one of the following consequences:
a) death of the patient, user or other person
b) serious deterioration, temporary or permanent impairment of the state of health of the patient, the user or another person;
c) a serious threat to public health

Where is the study run from?
Hospital Isola Tiberina – Gemelli Isola, Italy.

When is the study starting and how long is it expected to run for?
September 2023 to May 2025.

Who is funding the study?
Ethicon (UK)

Who is the main contact?
1. Prof Vincenzo Tondolo, vincenzo.tondolo@fbf-isola.it
2. Prof Sergio Alfieri, sergio.alfieri@fbf-isola.it

# Contact information

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Scientific, Principal investigator, Public

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# Additional identifiers

# Study information

**Scientific Title**
Absolok® haemostatic evaluation in colorectal surgery: a single-centre randomized open-label pilot clinical trial

**Acronym**
Absolok trial

**Study objectives**
According to the hypothesis, Absolok clips would relate to a lower incidence of perioperative incidence of bleeding as compared to the Hem-o-lock ones. Consequently, the primary objective of our study will be the comparison between Absolok and Hem-o-lock in terms of hemostatic capability.

As further analysis, intraoperative data (namely operative time, intraoperative complications) and postoperative data (time to flatus, postoperative complications, length of hospital stay) will be compared between the two study cohorts. This analysis will be particularly focused on the potential clips-related complications.

## Ethics approval required
Ethics approval required

## Ethics approval(s)
approved 25/09/2023, Ethical Committee of Lazio 3 (Agostino Gemelli University Hospital Foundation IRCCS Catholic University of the Sacred Heart Largo Francesco Vito, 1, Rome, 00168, Italy; +39 0630151; comitatoetico.lazioarea3@pec.policlinicogemelli.it), ref: ID 6090

## Primary study design
Interventional

## Allocation
Randomized controlled trial

## Masking
Open (masking not used)

## Control
Active

## Assignment
Parallel

## Purpose
Device feasibility, A comparative analysis of the haemostatic efficacy for each clipped vessel (graded with Siegel's scale) intraoperative and short-term postoperative outcomes was performed.

## Study type(s)

## Health condition(s) or problem(s) studied
Haemostatic performance at the transection site for each clipped vessel during curative colorectal resection.

## Interventions
Type of study
Monocentric randomized open-label pilot clinical trial.

All patients undergoing colorectal resections (namely, right hemicolectomies, left hemicolectomies and rectal resections) will be included in the study, independently of the type of approach to be performed (open, laparoscopic, robot-assisted) The following steps are required in all cases, independently of type of surgical clips used.

Eligible participants were randomized 1:1 to Absolok® or Hem-o-Lok® using a computer-generated allocation sequence (PASS 2019) without stratification.

The following steps are required in all cases, independently of type of surgical clips used.

Right hemicolectomy

The ileocolic pedicle is identified by gently placing the ileocecal junction on stretch by pulling it away from the retroperitoneum towards the right lower quadrant. Once identified, the peritoneum of the mesentery just inferior to the vessel is opened using a cautery. The avascular plane between the mesocolon and retroperitoneum is then developed using blunt dissection to lift the vessel away from the retroperitoneum. The medial dissection of the ileocolic artery and vein is carried to its origin from the superior mesenteric vessels. Complete dissection in this bloodless plane is performed laterally over Gerota's fascia to the abdominal wall laterally and cranially over the duodenum and head of the pancreas entering the lesser sac. Toldt's fascia is carefully protected on the retroperitoneum to protect the ureter and duodenum. Once the ileocolic vessels are isolated, they are divided between surgical clips (Hem-o-Lok® or Absolok®, according to the randomization). The right colic vessels have more variation and can branch from the middle colic artery or directly off the superior mesenteric artery and can also be transected by means of a Hem-o-Lok® or Absolok® clip, according to the group assignment. After completion of the vascular phase and adequate mobilization of the right colon, the greater omentum is divided, and the gastrocolic ligament is divided using an energy device (mostly ultrasound). The right branches of the middle colic vessels are then identified and divided with surgical clips (Hem-o-Lok® or Absolok®, according to group assignment). The terminal ileum is evaluated and divided at a site of healthy, well-perfused bowel. A linear cutting stapler is used to divide the bowel. The transverse colon is divided into a healthy and well-perfused area with a cutting stapler. Division of the mesentery and the resulting pulsatile bleeding can confirm good perfusion to the segment. The specimen is then removed from the field, and anastomosis is performed using a manual single-layer extramucosal isoperistaltic suture (open technique) or a semiautomatic mechanical isoperistaltic suture with a barbed monofilament to close the service enterotomy (laparoscopic–robotic intracorporeal technique). A Pfannestiel incision is routinely adopted for the latter cases to extract the specimen.

Left hemicolectomy

A medial to lateral approach is generally the preferred approach unless the surgeon is unable to safely identify the anatomy. This approach allows the surgeon to safely separate the left colonic mesentery from the retroperitoneum and protect the ureter, retroperitoneal blood vessels, and sympathetic nerves. The exposure is facilitated by reflecting the small bowel out of the pelvis using a lithotomic right lateral position of the table. Once the inferior mesenteric artery pedicle is placed on a gentle stretch, a mesenteric window is created with cautery. The pedicle is lifted upwards, and a gentle blunt dissection is performed in the proper congenital fusion plane between the Gerota and Told's fascias. Once the mesentery is lifted off, the retroperitoneum, left ureter and gonadal vessels are swept away from the pedicle. The inferior mesenteric artery is thus isolated and clipped by means of Hem-o-Lok® or Absolok® clips, according to the group assignment. The inferior mesenteric vein is then isolated and ligated by means of Hem-o-Lok® or Absolok® clips, according to the group assignment. The colon is further mobilized off the retroperitoneum by dissection through this thin peritoneal layer. The remainder of the descending colon is mobilized off the lateral retroperitoneal attachments, and the splenic flexure is routinely taken down to achieve a tension-free anastomosis. Typically, the lateral dissection continues, rolling the colon mesentery medially away from Gerota's fascia over the kidney. Renocolic, splenocolic, and phrenicocolic attachments are released, and a colo-epiploic separation is obtained using an energy device (mostly ultrasound). Finally, the remaining peritoneal attachments are divided, taking care to protect both ureters and the sympathetic nerves at the sacral promontory. An energy device is used to thin out the rectal mesentery to prepare the rectum for transection after it is cut between clips (Hem-o-Lok® or Absolok®,

according to the group assignment), and the superior rectal artery and vein running medially in the mesorectum. The rectum is transected with a linear cutter stapler, ideally in one single firing. A Pfannenstiel incision for extraction is preferred because of its lower risk of incisional hernia formation and wound complications in cases involving a laparoscopic-robotic approach. End-to-end anastomosis is performed according to the Knight–Griffen technique by means of a mechanical circular stapler.

Rectal resections
The same steps of the left hemicolectomy are adopted for rectal resections, and the dissection is extended over the extraperitoneal rectum. Intrapelvic dissection is carried out through standardized planes. Dissection of the rectum starts with an incision of the peritoneal fold in the pelvis. Mesorectal excision starts posteriorly by dissection through Heald's "holy plane"; it is carried on towards the lateral region of the rectum, sparing the lateral part of the lateral rectal ligaments, and extends on the anterior side in front of Denonvilliers' fascia. End-to-end anastomosis is performed according to the Knight–Griffen technique (Knight–Griffen results of double stapling by means of a mechanical circular stapler).

Primary endpoint
The primary endpoint will be the percentage of subjects who achieve Grade 3 or lower hemostasis for each vessel clipped and transected, according to the grading scale (19) reported below:
o Grade 1: no bleeding at transection site;
o Grade 2: minor bleeding at transection site, no intervention needed;
o Grade 3: minor bleeding at transection site, mild intervention needed, use of compression, basic energy devices (monopolar and/or bipolar)
o Grade 4: significant bleeding (e.g., pulsatile blood flow, venous pooling) requiring intervention such as extensive coagulation or ligation with use of additional hemostatic measures (e.g., hemoclips, staples, sutures, fibrin sealants, other advanced energy products).

Secondary endpoint
The secondary endpoint of the study will be the evaluation of the potential influence of the type of clip employed on the intraoperative and postoperative courses. For this purpose, the following outcomes will be evaluated:
o operative time
o intra-operative complications
o time to flatus
o postoperative complications
o length of hospital stay

## Intervention Type
Device

## Phase
Phase II

## Drug/device/biological/vaccine name(s)
Absolok clips

## Primary outcome(s)

1. Safety and haemostatic power of Absolok® and Hem-o-Lok® clips during colorectal surgical procedures measured using the haemostatic efficacy for each clipped vessel, which was graded according with Siegel's scale intraoperatively at surgery

2. Short-term postoperative outcomes measured using data collected on postoperative complications, graded according to Clavien-Dindo classification, during the postoperative period (within 30 days from surgery), at one time point

### Key secondary outcome(s))

### Completion date
11/05/2025

## Eligibility

### Key inclusion criteria
All >18 years patients undergoing curative colorectal resection for benign and malignant disease, including right hemicolectomies, left hemicolectomies and rectal resections

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
18 years

### Upper age limit
90 years

### Sex
All

### Total final enrolment
258

### Key exclusion criteria
1. Patients aged < 18 years
2. Inability to give informed consent
3. Emergent surgery
4. Previous colorectal surgery
5. Uncontrollable diabetes mellitus that needs continuous intravenously administered insulin
6. History of myocardial infarction or unstable angina pectoris within 6 months
7. Cardiac failure, New York Heart Association (NYHA) III degree
8. Anticoagulant therapy
9. Liver cirrhosis, Child-Pugh class C
10. Active hepatitis
11. Chronic renal failure requiring hemodialysis

**Date of first enrolment**
26/09/2023

**Date of final enrolment**
11/04/2025

# Locations

**Countries of recruitment**
Italy

# Sponsor information

**Organisation**
Ethicon (UK)

# Funder(s)

**Funder type**

**Funder Name**
Ethicon

**Alternative Name(s)**
Ethicon USA, LLC., Ethicon, Inc., Ethicon Suture Laboratories., G.F.Mersons Limited

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
For-profit companies (industry)

**Location**
United States of America

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not expected to be made available

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol file | version 1.1 | 28/02/2022 | 05/02/2026 | No | No |
| Statistical Analysis Plan | | | 05/02/2026 | No | No |