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AIDE STUDY SYNOPSIS

Protocol Title:

Multicenter Observational Study to Support Decision-Making Between Primary Anastomosis and Colostomy in Emergency Surgery for Complicated Diverticulitis

Acronym: AIDE/OBS

Protocol Version: 2.0 – March 2026

Study Duration: 24 months

Background and Rationale

Complicated diverticulitis with peritonitis (Hinchey III–IV) remains a condition characterized by marked intraoperative decision-making variability, in the absence of standardized criteria to guide the choice between primary anastomosis and Hartmann's procedure. Artificial intelligence (AI) and computer vision are emerging tools that may integrate clinical data and intraoperative images in order to support the surgeon during the decision-making process.

This study does not involve any therapeutic intervention and does not modify current clinical practice.

Objectives

Primary Objectives

- To reduce the colostomy rate in patients undergoing emergency surgery for acute complicated diverticulitis.
- To collect clinical data and intraoperative images/videos from patients undergoing emergency surgery for acute complicated diverticulitis, in order to identify the factors influencing the choice between primary anastomosis and Hartmann's colostomy, and to reproduce such decision-making patterns through AI algorithms.
- To develop a software tool capable of analyzing intraoperative images according to predefined parameters in order to estimate the risk of complications when performing left colectomy with anastomosis.

The data collected in this phase will constitute the basis for the future development of a standardized dataset to support the creation of decision-support tools in subsequent phases.

Secondary Objectives

- To identify the clinical and intraoperative parameters that influence surgical decision-making.
- To assess the quality and feasibility of intraoperative image/video collection across the participating centers.
- To explore the role of fluorescence imaging (ICG) in intraoperative bowel perfusion assessment and in the surgeon's decision-making process.

Study Design

This is a multicenter, observational, non-interventional study.

It includes both retrospective and prospective patients undergoing emergency colorectal resection through a minimally invasive approach.

The following data will be collected:

- Clinical data (demographics, comorbidities, imaging findings, intraoperative parameters, outcomes);
- Visual data (anonymized laparoscopic or robotic images/videos);
- Surgical reasoning (factors that guided the intraoperative decision).

The study does not alter the diagnostic or therapeutic pathway, nor does it interfere with operating room workflow. Patient treatment will remain fully consistent with standard clinical practice.

Inclusion Criteria

- Age ≥ 18 years
- Informed consent obtained before data collection and acquisition of surgical images/videos, in accordance with local regulations
- Acute complicated diverticulitis requiring urgent surgery
- Minimally invasive surgical approach (laparoscopic/robotic)
- Hartmann's procedure or resection with anastomosis (± ileostomy)

Exclusion Criteria

- Open surgery
- Non-diverticular disease
- Lack of informed consent

Endpoints

Primary Endpoint

Creation of a structured clinical and visual dataset, obtained through the prospective collection of clinical data and intraoperative images/videos from patients undergoing emergency surgery for complicated diverticulitis, aimed at analyzing the factors influencing the intraoperative choice between primary anastomosis and Hartmann's procedure, with the long-term goal of reproducing this decision-making process through AI algorithms.

Secondary Endpoints

- Frequency and quality of image acquisition for each predefined surgical phase
- Descriptive analysis of observed decision-making patterns (anastomosis vs Hartmann)
- Postoperative outcomes (anastomotic leak, complications, stoma management)
- Assessment of the technical and organizational feasibility of multicenter collection of standardized clinical and visual data

Data Collection, Management, and Storage

Site of Data Collection

Data will be collected exclusively at authorized participating clinical centers.

At each center:

- clinical data will be obtained from the medical records;
- images/videos will be obtained from laparoscopic or robotic platforms;
- the surgeon's report form will be completed at the end of the procedure.

The sponsor center, IRCCS San Raffaele, will be responsible for receiving the data and performing the related analyses.

Data Collection Procedures

Sixty-three centers have agreed to contribute to the collection of clinical and intraoperative visual data.

Each center will:

- extract clinical data in anonymized form;
- export images/videos without metadata, including no patient name, date/time, or procedure number;
- assign a unique AIDE-XXX code to each case;
- upload the data to a secure portal or send them on encrypted storage media.

The re-identification key will remain at the originating center and will not be transferred.

Data Storage

Anonymous data will be stored on a secure GDPR-compliant server. No data will be uploaded to non-European or non-GDPR-compliant cloud services.

Data Access

Access will be restricted exclusively to the PI and co-investigators at the coordinating center.

Data Transfer Between Centers

Only anonymized data will be transferred, through a secure platform or encrypted physical media (USB drive/hard disk).

Data Retention Period

Data will be retained for 10 years after study closure, in accordance with Italian and European regulations applicable to observational studies.

Purpose of Data Use

The data collected in this study phase will be used exclusively for:

- observational scientific research purposes;
- analysis of the clinical and intraoperative factors guiding surgical decisions in patients with complicated diverticulitis;
- scientific publications in aggregated and fully anonymized form.

No commercial use is planned.

Any future developments, including predictive models based on artificial intelligence, will be the subject of specific protocols requiring new ethical approval.

Sample Size

As this is a pilot study, no formal sample size calculation is required. However, the aim is to collect approximately 150 cases (75 Hartmann's procedures and 75 anastomoses).

Recruitment will be competitive. Each center will contribute data from at least 5 cases.

Descriptive statistical analyses and implementation of AI algorithms are planned.

Ethical Aspects

This is a non-profit, observational study, with no additional therapeutic or diagnostic intervention.

No additional risk is expected for participating patients.

Clinical data and videos collected for the study will be anonymized and coded according to the procedures established by the participating centers.

Images and videos will be stripped of any identifying elements, including face, voice, and sensitive data.

Written informed consent for the use of data for research purposes will be obtained by the recruiting clinical centers.

The study complies with the GDPR and with applicable national regulations concerning personal data protection.

Study results will be disseminated in aggregated and anonymized form and used exclusively for scientific research purposes.

The data collected will help improve understanding of intraoperative decision-making factors in patients with complicated diverticulitis.

Any future developments, including AI-based decision-support models, will be addressed through separate protocols to be submitted for independent ethical review.