REsection of the **ME**sentery vs **A**nastomotic configuration and **SU**rgical **Re**currence.

REMEASURE Trial in Crohn's Disease V2.1

Resection of the mesentery with functional end-to-end anastomosis vs Kono-S anastomosis in preventing relapse after ileocolic resection for primary Crohn's Disease.
A prospective, monocentric, randomized trial.

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INFORMED CONSENT FORM_ 09/09/2025

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Torino, September 9, 2025

"**Re**section of the **me**sentery vs Kono-S **a**nastomosis in preventing **su**rgical **re**currence for primary Crohn Disease: the **REMEASURE** prospective, randomized, controlled trial" Clinical Trial. Gov number NCT07164209

Remeasure informed consent

Sincerely

Michela Mineccia, MD

PATIENT INFORMATION AND CONSENT FORM

(Confidential document)

According to the provisions of the European General Data Protection Regulation ("GDPR") and National Data Protection Law, we ask that you read carefully this patient information.

Dear Sir/Madam.:

You have been diagnosed with Crohn Disease and invited to participate to a Multicenter Clinical Trial guided from the Ospedale Mauriziano "Umberto I", Torino (S.C. Chirurgia Generale ed Oncologica), Italia.
Researchers study cases such as your to improve diagnosis and therapies in clinical research.
Participation shall be voluntary and each patient will have sufficient time for take his decision. You will find the information on clinical trial below, which you'll have to read carefully.

Research finality and description of clinical trial

This trial regards patients undergoing ileo-colic resection for Crohn Disease.
Data from scientific literature show that after those kinds of operations relapses of disease occur very frequently and about 40% of patients will need a second operation due to a surgical recurrence.
Many Authors have studied new strategies to prevent relapse of disease.
The most important are:

- The creation of a new type of bowel anastomosis (Kono-S anastomosis)
- The removal of the mesentery (the soft tissue involving vessels feeding bowel and lymphatic vessels)

Both surgical strategies represent a way to reduce the relapse of disease in the site of anastomosis.
Both strategies are sure and not associated with a high rate of morbility or mortality, being consolidated in common clinical practice and have been performed in various surgical procedures but they were never directly compared.
In fact, it remains unclear which one is more effective in reducing surgical recurrence.

The trial involves patients with CD from many Italian, European, American and Asian high volume Centers with specialization in treatment of Inflammatory Bowel Disease.
Half of participants will be treated with "Kono" anastomosis and half will be subjected to the removal of mesentery of the diseased bowel.

The assignment of patients to one group or another is not at the discretion of the investigators but is done through the mechanism of randomization.

The present trial is approved by the Ethical Committee of the two Principal Investigators and by the Independent Ethical Commettee of you Center.

- The participation is voluntary and if you wish to withdraw during the study you can do so at any time.
- Alternatively you will be treated according to current clinical practice, i:e. without removing the mesentery and without Kono anastomosis

Procedures

- Once the consent is signed the physician will assess the eligibility for the study and you will perform the scheduled tests that are part of the normal therapeutic approach
- All expenses are handled as if you were e receiving normal medical care.
- Participation in this study does not provide remuneration.

Data Treatment

Your medical data and certain other information, such as geographical location and gender, in an anonymised way, may be used for studies at a local, national, international level. When the aforementioned information is anonymised, no reference to your identity is possible for anyone.
Please note that we process your personal data exclusively within the necessary scope and exclusively based on your consent.
The confidentiality of data is ensured in accordance with current regulations.
Any data used in research studies by any doctor or healthcare professional at a national or international level will be anonymised. This means the data used does not refer to any information that allows your identification.

Access to your personal data (i.e. name, address, email address), will be properly restricted to the attending physician/staff and will not be known by anyone else.
The promoter of the study for each Center guarantees compliance with National and International guidelines in compliance with Code regarding the protection of personal data.

PATIENT'S INFORMED CONSENT TO PARTICIPATION IN THE CLINICAL TRIAL

Resection of the mesentery with functional end-to-end anastomosis vs Kono-S anastomosis in preventing relapse after ileocolic resection for primary Crohn's Disease (REMEASURE).

A prospective, international, multicenter, randomized trial.

PATIENT DECLARATION

With the signature below I certify that:

• The doctor named below explained to me the procedure of the study, the expected effects, the possible advantages and disadvantages, and the potential risks. If I would like more information about this study, I can contact the study doctor.
• I have read and understood the patient information form produced for this study. My questions regarding participation in the study have been satisfactorily answered. I can keep the information form and will receive a copy of my signed informed consent.
• I had enough time to make my decision.
• My participation in this study is voluntary. I can withdraw my participation at any time without giving any reasons and without any repercussions on the continuation of medical assistance.
• I will receive a copy of the patient information form and a copy of the signed consent form.

NAME AND SURNAME _____

SIGNATURE _____DATE: _____

PHYSICIAN'S STATEMENT REQUESTING CONSENT

I declare that I have fully explained this study to the patient. The information provided, including on the risks and benefits, was sufficient for the informed decision.

NAME AND SURNAME of the PHYSICIAN REQUESTING CONSENT

_____

SIGNATURE _____DATE: _____