Recruiting

Lumeneye Rectoscope for Assessment on Tumor Response After Total Neoadjuvant Treatment in Rectal Cancer (LUMEVAL)

ClinicalTrials.gov ID NCT06189846

Sponsor Bordeaux Colorectal Institute Academy

Information provided by Bordeaux Colorectal Institute Academy (Responsible Party)

Last Update Posted 2025-02-05

Study Details Tab

Study Overview

Brief Summary

The objective of this prospective international cohort is to evaluate the LUMENEYE rectoscope for assessment on tumor response after total neoadjuvant treatment in rectal cancer.

Patients included in this study will be patients who initially will be good candidates for organ preservation. The participating centers are all expert centers in tumor assessment.

All patient assessments after neoadjuvant treatment for rectal adenocarcinoma will be included in each centre.

Detailed Description

The recent validation of the Total Neoadjuvant Treatment (TNT) protocol and the improvement of techniques for evaluating tumor response are two major factors in the development of organ preservation in rectal cancer.

Although recent publications have shown promising results of the two organ preservation strategies, Watch & Wait and Local excision, with a low oncological risk, some challenges remain to be addressed before the generalization of rectal preservation in clinical practice.

Among these challenges, the improvement of patient selection and methods for evaluating tumor response appear necessary. The monitoring scheme for the tumor response has not yet been clearly established, but a 6 months programme of tumor response assessment has been recently published (Boubaddi EJSO 2023). Monitoring must consist of a clinical assessment (rectal examination and/or rectoscopy) and additional morphological examinations (rectal MRI) every two months.

Tumor response after neoadjuvant treatment by MRI (TRG 1-5, Tumor Regression Grade) is established as a reliable method of tumor response assessment and accurate diagnosis of complete clinical response. However, discrepancies between clinical examination and radiological MRI may exist and patients undergoing watch-and-wait who develop local regrowth due to mistake in initial tumour response assessment are at higher risk for development of distant metastases (Sao Juliao DCR 2023) with a poor impact on long term oncological results.

The development of the LumenEye digital rectoscope by the SurgEase company enables a comfortable and efficient scoping for the user and the patient (Lewis J BJGP Open 2022). With high quality images of Full HD images and video associated with a secure and connected intuitive software platform, this endoscope can have its place in the monitoring of tumor response.

The contribution of this technology to the monitoring of the tumor response needs to be assessed. This medical device is CE marked and used in its intended purpose.

The objective of this study is to evaluate the complete and/or nearly complete response with LumenEye digital rectoscope.

Official Title

Prospective Study Incorporating LUMENEYE Rectoscope for Assessment on Tumor Response After Total Neoadjuvant Treatment in Rectal Cancer

Conditions

Rectal Cancer

Intervention / Treatment

- Device: International Cohort

Other Study ID Numbers

Study Start (Actual)

2024-01-04

Primary Completion (Estimated)

2025-07

Study Completion (Estimated)

2025-07

Enrollment (Estimated)

100

Study Type

Observational [Patient Registry]

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Health Checkup (https://medlineplus.gov/healthcheckup.html)

FDA Drug and Device Resources (https://clinicaltrials.gov/fda-links)

Contacts and Locations

This section provides contact details for people who can answer questions about joining this study, and information on where this study is taking place.

To learn more, please see the Contacts and Locations section in How to Read a Study Record (https://clinicaltrials.gov/study-basics/how-to-read-study-record#contacts-and-locations).

Study Contact

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Study Contact Backup

Name: Stéphanie GUILLON
Phone Number: +33 668686805
Email: s.guillon@bordeaux-colorectal-institute.fr

This study has 8 locations

France

Bordeaux, France
Recruiting
Clinique Tivoli-Ducos - Bordeaux Colorectal Institute
Contact : Quentin DENOST, Prof
+33547501575
q.denost@bordeaux-colorectal-institute.fr

Marseille, France
Recruiting
Hôpital Européen de Marseille
Contact : Antoine CAMERLO

Paris, France
Not yet recruiting
Hôpital Saint-Antoine - APHP
Contact : Jérémie LEFEVRE

Rouen, France
Not yet recruiting
CHU de ROUEN
Contact : Jean-Jacques TUECH

Italy

Milan, Italy
Recruiting
Humanitas Research Hospital
Contact : Antonino SPINELLI

Netherlands

Amsterdam, Netherlands
Not yet recruiting
Amsterdam UMC
Contact : Roel HOMPES

Spain

Barcelona, Spain
Recruiting
University Hospital Vall D'Hebron
Contact : Eloy ESPIN

United Kingdom

London, United Kingdom
Not yet recruiting
Imperial College London
Contact : James KINROSS

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study-basics/learn-about-studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Patient ≥ 18 years
- Histologically confirmed diagnosis of adenocarcinoma of the rectum,
- Patient who received radiotherapy and chemotherapy (TNT) or immunotherapy
- Stage cT2T3
- cN0 or cN1 (≤ 3 positive LN or size ≤ 8 mm)
- no metastases
- Baseline Tumour size ≤ 5 cm (MRI)
- Baseline Tumour ≤ 8 from anal verge
- Ability to consent.
- Oral agreement after reading information letter

Exclusion Criteria:

- Tumour cT1 or cT4
- Baseline Tumour size > 5cm
- Invaded external sphincter or levator muscle
- Tumour cN2 (> 3 positive LN or size > 8 mm)
- Metastasis
- History of Inflammatory bowel disease
- Patient with a history of pelvic radiotherapy or chemotherapy
- Pregnant patients
- Protected adults (individuals under guardianship by court order).

Study Population

These are patients with small rectal cancer, initially good candidates for organ preservation and whose evaluation is done by clinical and radiological examination and with the Lumeneye rectoscope

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Sampling Method

Non-Probability Sample

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Observational Model : Cohort
Time Perspective: Prospective
Target Follow-up Duration: 6 Months

Groups and Interventions

Intervention/Treatment
Device: International Cohort • Assessing tumour response following neoadjuvant treatment in rectal cancer include : ◦ Digital rectal examination ◦ Rectal MRI ◦ Rectoscopy (Lumeneye device) The monitoring of tumour response intervals up to 6 months following completion of the neoadjuvant treatment at 8 weeks, at 16 weeks, at 24 weeks after the end of neoadjuvant treatment.

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
The rate of complete and/or nearly complete response	To evaluate the complete and/or nearly complete response with LumenEye digital endoscopescope	From 8 weeks to 24 weeks after the end of radiotherapy

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame

Agreement for grading rectal tumour response between the endoscopic and MRI assessment of tumour response	To evaluate the concordance between the endoscopic and MRI assessment of tumor response	From 8 weeks to 24 weeks after the end of radiotherapy
Agreement for grading rectal tumour response between the clinical and endoscopic assessment of tumour response	- To evaluate the concordance between the clinical and endoscopic assessment of tumor response.	From 8 weeks to 24 weeks after the end of radiotherapy
Agreement for grading rectal tumour response between the clinical and MRI assessment of tumour response.	To evaluate the concordance between the clinical and MRI assessment of tumor response.	From 8 weeks to 24 weeks after the end of radiotherapy
Interobserver agreement for grading rectal tumour response using a digital	To assess the interobserver reproducibility of endoscopic response with LumenEye digital endoscope within 6 months after the end of neoadjuvant treatment.	From 8 weeks to 24 weeks after the end

rectoscope platform		of radioth erapy
Rate of changing attitude after using the digital rectoscope platform (intra-observer changing management).	To evaluate the contribution of the digital ectoscope platform in the surgeon's decision-making	From 8 weeks to 24 weeks after the end of radioth erapy

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Bordeaux Colorectal Institute Academy

Investigators

- Study Director: Quentin DENOST, Bordeaux Colorectal Institute

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted

2023-12-19

First Submitted that Met QC Criteria

2023-12-19

First Posted
2024-01-05

Study Record Updates

Last Update Submitted that met QC Criteria
2025-02-03

Last Update Posted
2025-02-05

Last Verified
2025-02

More Information

Terms related to this study

Additional Relevant MeSH Terms

Colorectal Neoplasms
Intestinal Neoplasms
Gastrointestinal Neoplasms
Digestive System Neoplasms
Neoplasms by Site
Neoplasms
Digestive System Diseases
Gastrointestinal Diseases
Intestinal Diseases
Rectal Diseases
Rectal Neoplasms

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

No

Drug and device information, study documents, and helpful links

Studies a U.S. FDA-Regulated Drug Product

No

Studies a U.S. FDA-Regulated Device Product

No

Product Manufactured in and Exported from the U.S.

No