Long - Term Low Anterior Resection Syndrome

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT03920202	COMPLETED	APRIL 18, 2019	APRIL 18, 2019

STUDY DESCRIPTION

Brief Summary

Data assessing the long-term bowel dysfunction following low anterior resection is still lacking. The aim of this study is to evaluate late functional results of patients who underwent rectal resection for rectal cancer. This included calculating LARS and Wexner score and identifying possible risk factors of late postoperative bowel disorders.

Condition or Disease: Bowel; Functional Syndrome

Intervention/treatment:

Phase: N/A

DETAILED DESCRIPTION

For the last almost 30 years, the gold standard treatment for RC is low anterior resection (LAR) with total mesorectal excision (TME). Unfortunately, up to 80 % of patients undergoing LAR will suffer of bowel dysfunction including faecal urgency, frequent bowel movements, tenesmus or so called Low Anterior Resection Syndrome (LARS). Simply it has been defined as "disordered bowel function after rectal resection, leading to a detriment in quality of life". Same year LARS score was developed. This tool is easy to use and has been internationally and in Lithuania validated. Wexner score is another tool for evaluation of faecal continence.

There are only five studies investigating long-term results after rectal surgery and influence it has on patients' daily life. In one study 47 of 51 patients experienced LARS following ultra-low anterior resection after average 6.5 years. Another study recently reported major LARS in 46% of the patients with the mean median follow-up of 14.6 years. Others showed that 47.5% of patients still experience LARS symptoms at a follow-up period of 13.7 years. Just recently published study assessed bowel function 12 years in patients undergoing rectal resection with or without preventing ileostomy. Authors found that 63 (72%) patients of 87 experienced LARS symptoms with more than a half complaining of major LARS. Moreover, just last year a study published showing that 73% of patients had LARS at first follow up 5 years after the surgery. During the second visit (another 5 years later) same numbers were seen.

The aim of this study was to evaluate late functional results of patients who underwent rectal resection for rectal cancer. This included calculating LARS and Wexner score and identifying possible risk factors of late postoperative bowel disorders.

STUDY DESIGN

Study Type: Observational [Patient Registry]

Estimated Enrollment : 67 participants

Intervention Model : N/A

Masking: N/A

Primary Purpose: N/A

Official Title: Long - Term Bowel Dysfunction Following Low Anterior Resection

Actual Study Start Date: January 2012

Actual Primary Completion Date: January 2014

Actual Study Completion Date: December 2018

OUTCOME MEASURES

Primary Outcome Measures: 1. Bowel function assessment using Low anterior resection syndrome questionnaire [Time Frame: 5 years]
Bowel function following low anterior resection surgery for rectal cancer will be assessed using Low anterior resection syndrome score (LARS score - simple 5 question questionnaire). LARS score is a tool consisting of five items, which are as follows: incontinence due to flatus (score range from 0 to 7), incontinence due to liquid stools (score range from 0 to 3), frequency of bowel movements (score range from 0 to 5), clustering (score range from 0 to 11) and urgency (score range from 0 to 16). The severity of each item is calculated on a scale ranging from 0 to 42, with a score of 0-20 (no LARS), 21-29 (minor LARS) and 30-42 (major LARS).

Secondary Outcome Measures:
1. Risk factors: age [Time Frame: 5 years]
Risk factors for having worse bowel function following low anterior resection for rectal cancer - age: older patients (>55years) might have worse bowel function
2. Risk factors: type of surgical procedure [Time Frame: 5 years]
Risk factors for having worse bowel function following low anterior resection for rectal cancer - type of surgery: rectum resection with total mesorectal excision vs partial mesorectal excision will lead to worse functional outcome.
3. Risk factors: preoperative chemoradiotherapy [Time Frame: 5 years]
Risk factors for having worse bowel function following low anterior resection for rectal cancer - preoperative chemoradiotherapy might lead to worse functional outcome.

ELIGIBILITY CRITERIA

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
- patients diagnosed with rectal cancer without metastasis
- signed consent form
- more than 5 years following the surgery

Exclusion Criteria:
- unwilling to participate
- stage IV disease
- change in operative plan - end colostomy formed

CONTACTS AND LOCATIONS

Contacts

Locations

Lithuania	National Cancer Institute	Vilnius

Sponsors and Collaborators

National Cancer Institute, Lithuania

Investigator

Study Chair :	Narimantas Samapavicius, Prof.	Klaipėda University

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MORE INFORMATION

Responsible Party :	National Cancer Institute, Lithuania
ClinicalTrials.gov Identifier :	NCT03920202
Other Study ID Numbers :	LongLARS
First Posted :	April 18, 2019
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Individual Participant Data (IPD) Sharing Statement:	
Plan to Share IPD:	No
Plan Description:	Only results of the study will be shared
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No
Keywords provided by National Cancer Institute, Lithuania:	*Low anterior resection syndrome score* *Rectal cancer* *Bowel dysfunction Low anterior resection syndrome* *Quality of life*
Additional relevant MeSH terms :	*Irritable Bowel Syndrome* *Syndrome*