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# Level of arterial ligation in rectal cancer surgery

**Submission date**
09/11/2012

**Recruitment status**
No longer recruiting

**Registration date**
18/12/2012

**Overall study status**
Completed

**Last Edited**
01/02/2022

**Condition category**
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Rectal cancer is treated with surgery to partially or totally remove the rectum along with the surrounding tissue containing blood vessels and lymph nodes. It is important to remove the local lymphatic system because it may contain cancer that has spread (metastases). Lymph nodes are found by the artery that supplies blood to the rectum. The extent of lymph node removal is determined by where the artery is tied (ligated) by the surgeon. Different surgeons remove more or less of the lymphatic system. There are usually two locations of arterial ligation, called “high tie” and “low tie”. The aim of our study is to find out whether the level of arterial ligation affects the incidence of complications after the operation and the patients’ long-term survival.

Who can participate?
Patients aged 18 or over undergoing surgery for rectal cancer

What does the study involve?
Participants are randomly allocated to one of two groups. One group undergoes high arterial ligation, and the other low arterial ligation. After hospital discharge participants are invited to routine follow-up visits every three months over the next 5 years. Participants should contact the department in case of any adverse symptoms or events. Quality of life, disease recurrence and complications are assessed.

What are the possible benefits and risk of participating?
There are neither direct benefits nor special risks of participating in the study since all of the proposed methods of the surgery are normally performed by different surgeons. Both methods of arterial ligation are recommended in rectal cancer treatment. Participation in the study will improve treatment for rectal cancer in the future by determining the best range of lymphatic system removal.

Where is the study run from?
Gdynia Centre of Oncology of Maritime Hospital in collaboration with the Medical University of Gdansk, Poland

When is the study starting and how long is expected to run for?
September 2009 to June 2019

Who is funding the study?
Foundation for the Development of Surgery [Fundacja na Rzecz Rozwoju Chirurgii], Gdynia, Poland

Who is the main contact?
Prof. Wieslaw Janusz Kruszewski
wjkrusz@gumed.edu.pl

# Contact information

### Type(s)
Scientific

### Contact name
Prof Wieslaw Kruszewski

### ORCID ID
http://orcid.org/0000-0002-5929-5232

### Contact details
Maritime Hospital
Gdynia Centre of Oncology
Powstania Styczniowego 1
Gdynia
Poland
81-519
+48 (0)587 260 250
wjkrusz@gumed.edu.pl

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
N/A

# Study information

### Scientific Title
Oncological and surgical outcome after high versus low ligation of inferior mesenteric artery during curative surgery from rectal cancer

### Study objectives
Oncological and surgical outcome after ligation and division of superior rectal artery just beneath the origin of left colic artery (low tie) is not inferior than after ligation of inferior mesenteric artery at its origin (high tie) during curative surgery for rectal cancer.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Bioethics for Research Committee of Medical Univeristy of Gdañsk, Poland ref: NKEBN/373/2009

## Study design
Randomised trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied
Rectal cancer suitable for curative R0 resection with or without prior neoadiuvant treatment

## Interventions
The ligation and division of inferior mesenteric artery at its origin from aorta or just beneath the origin of the left colic artery from inferior mesenteric artery during curative R0 resection from rectal cancer.

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome measure
1. Postoperative mortality and morbidity (special reference to the rate of clinical anastomotic leakage)
2. The need for splenic flexure mobilization
3. The number of lymph nodes resected and their pathological estimation
4. Need for blood transfusion
5. Time to disease recurrence
6. Way of spread of disease
7. Cancer related death rate
8. Overall survival

### Secondary outcome measures
1. Permanent stoma rate
2. The rate of stoma reversal
3. Quality of life (QLQ C30 questionnaire)

### Overall study start date
01/09/2009

### Completion date
30/06/2019

## Eligibility

### Key inclusion criteria
1. Adult patient with the history of any other neoplasm than rectal and skin cancer
2. Any history of colorectal surgery except the laparoscopic ileostomy in patient awaiting for radical treatment of rectal cancer.

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
At least 120

### Total final enrolment
130

### Key exclusion criteria
1. Urgent operation
2. Potentially unresectable disease
3. Comorbid condtions excluding the possibility of standard therapy
4. T4 tumour
5. Any other malignant neoplasm except skin cancer
6. Synchronic distant metastases
7. Lack of patient consent for participation in the study

### Date of first enrolment
22/04/2010

### Date of final enrolment
08/03/2016

## Locations

**Countries of recruitment**
Poland

**Study participating centre**
**Maritime Hospital**
Powstania Styczniowego 1 str.
Gdynia
Poland
81-519

# Sponsor information

**Organisation**
Szpital Morski [Maritime Hospital ]

**Sponsor details**
Gdynia Centre of Oncology
81-519 Gdynia
Powstania Styczniowego 1
Gdynia
Poland
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**Sponsor type**
Hospital/treatment centre

**Website**
http://www.szpital-morski.pl

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Foundation for the Development of Surgery [Fundacja na Rzecz Rozwoju Chirurgii] (Poland)

# Results and Publications

**Publication and dissemination plan**

Planned publication in 2021.

## Intention to publish date
01/06/2021

## Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

## IPD sharing plan summary
Other

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 16/07/2021 | 01/02/2022 | Yes | No |