

Level of arterial ligation in rectal cancer surgery

Submission date 09/11/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/12/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/02/2022	Condition category Cancer	<input type="checkbox"/> 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
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Contact information

Type(s)
Scientific

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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 Gdańsk, 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 neoadjuvant 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 conditions 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

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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