

Development of a chart that can be used to aid prediction of hidden cancerous growths in colorectal cancer patients before surgery

Submission date 08/03/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/03/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/02/2023	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Bowel cancer is a general term for cancer that begins in the large bowel. Depending on where the cancer starts, bowel cancer is sometimes called colon or rectal cancer.

Early diagnosis of cancer spreading to the lining of the abdomen (peritoneal metastasis (PM)) is crucial to optimal treatment selection and improvement of survival, but it remains a challenge due to the high rate of missed diagnosis on computed tomography (CT) images. The aim of this study was to develop a chart for the identification of PM status in colorectal cancer (CRC) patients.

Who can participate?

Patients undergoing surgery for colorectal cancer.

What does the study involve?

Patient records of enhanced CT and laparoscopic exploration from 30/08/2007 to 26/09/2019 were analysed.

What are the possible benefits and risks of participating?

None

Where is the study run from?

The Sixth Affiliated Hospital, Sun Yat-sen University (China)

When is the study starting and how long is it expected to run for?

June 2020 to June 2021

Who is funding the study?

This study was sponsored by the National Natural Science Foundation of China (grant No. 82103084) and the Sun Yat-sen University Clinical Research 5010 Program (grant No. 2019021).

Who is the main contact?

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Contact information

Type(s)

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Predicting preoperative occult peritoneal metastasis in colorectal cancer patients: Development and external validation of a nomogram and study of its utility

Acronym

OPM

Study objectives

Early diagnosis of peritoneal metastasis (PM) is crucial to optimal treatment selection and improvement of prognosis, but it remains a challenge due to the high rate of missed diagnosis on computed tomography (CT) images. The aim of this study was to develop a nomogram for identification of preoperative occult PM status in colorectal cancer (CRC) patients, which can serve as a potential decision-making support tool and guide individualized care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 17/06/2020, China Research Ethics Committee (Yuancun street, Guangzhou, Guangdong 510515, China; lunli66@126.com; +44 20-38379764), ref: 2020ZSLYEC-109

Study design

Observational longitudinal case-control study

Primary study design

Observational

Secondary study design

Case-control study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not applicable (retrospective study)

Health condition(s) or problem(s) studied

Predicting preoperative occult peritoneal metastasis in colorectal cancer patients

Interventions

All enrolled patients were initially diagnosed as PM-negative by CT readings, but later confirmed with the actual PM status during the laparoscopic exploration. The patients were divided into two cohorts: one training cohort (n = 552 from center 1) and one external validation cohort (n = 70 from center 2).

All enrolled patients underwent enhanced CT examinations within two weeks before operation. The total duration of observation was from the diagnosis to the postoperative histological confirmation. The total duration of follow-up was not applicable because this study aimed to develop a risk model rather than a prognostic model.

Intervention Type

Other

Primary outcome measure

The actual PM status confirmed using the intraoperative or postoperative histological evaluations at a single time point

Secondary outcome measures

The predictive accuracy measured using receiver operating characteristic curve and calibration curves at a single time point

Overall study start date

17/06/2020

Completion date

17/06/2021

Eligibility

Key inclusion criteria

Current inclusion criteria as of 28/03/2022:

1. Patients were diagnosed with CRC by endoscopy-biopsy pathology, combined with CT and/or other examinations
2. Patients had only one malignant primary tumor
3. Patients did not undergo previous resection of the primary tumor
4. Patients underwent both enhanced CT and laparoscopic exploration

Previous inclusion criteria:

1. Diagnosed CRC by endoscopy-biopsy pathology, combined with CT and/or other examination
2. With no other malignant primary tumours
3. With no previous abdominal malignancies or inflammatory diseases
4. With no previous resection of primary tumour
5. With both enhanced CT and laparoscopic exploration.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

500

Total final enrolment

662

Key exclusion criteria

Current exclusion criteria as of 28/03/2022:

1. Typical PM signs on CT
2. Other distant metastases
3. Previous inflammatory diseases

Previous exclusion criteria:

1. With typical PM signs on CT
2. With other distant metastases
3. Incomplete or missing information

Date of first enrolment

30/08/2007

Date of final enrolment

26/09/2019

Locations

Countries of recruitment

China

Study participating centre

The Sixth Affiliated Hospital, Sun Yat-sen University

No.26 Yuancun Road

Tianhe District

Guangzhou

China

510655

Study participating centre

Zhujiang Hospital, Southern Medical University

No.253 Gongye Road

Haizhu District

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Sponsor information

Organisation

The Sixth Affiliated Hospital of Sun Yat-sen University

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<https://www.zs6y.com>

Funder(s)

Funder type

Government

Funder Name

National Natural Science Foundation of China

Alternative Name(s)

Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, , National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhùi, NSFC, NNSF, NNSFC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

China

Funder Name

Sun Yat-sen University Clinical Research 5010 Program

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/01/2023

Individual participant data (IPD) sharing plan

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.
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IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/07/2022	02/08/2022	Yes	No