ISRCTN76852032 https://doi.org/10.1186/ISRCTN76852032

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

Registration date
16/03/2022

Overall study status
Completed

Last Edited
01/02/2023

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Diagnostic

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

Key secondary outcome(s))
The predictive accuracy measured using receiver operating characteristic curve and calibration curves at a single time point

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
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Study participating centre
Zhujiang Hospital, Southern Medical University
No.253 Gongye Road
Haizhu Distrcit
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Sponsor information

Organisation
The Sixth Affiliated Hospital of Sun Yat-sen University

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 Wěiyuánhuì, , 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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes