

Using tissue images and patient information to predict genetic changes in colorectal cancer

Submission date 17/09/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/09/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/09/2024	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Colorectal cancer (CRC) is a common type of cancer that can behave differently depending on genetic changes in the tumor. One of these genetic changes is called microsatellite instability (MSI), which can help doctors choose the best treatment and predict how the cancer will progress. However, current ways of predicting MSI are not always accurate for all patients. This study aims to develop a new method that combines information from tissue samples and patient medical records to better predict MSI in colorectal cancer.

Who can participate?

Adults who have been diagnosed with colorectal cancer confirmed through a tissue biopsy can participate in this study. Participants must be fully aware of their condition, have had tests done to check for certain genetic changes (such as MSI and mutations in RAS or BRAF genes), and be willing to sign a consent form. People who have other types of cancer, incomplete test results, or poor-quality tissue images will not be eligible to take part.

What does the study involve?

Participants in this study will not need to undergo any new medical tests. Instead, the study will use existing data, including tissue samples and test results from their previous treatments. Researchers will analyze the images of these tissue samples using advanced computer methods, combining the findings with patient medical records to develop a new prediction model.

What are the possible benefits and risks of participating?

There are no direct health benefits or risks for participants in this study, as no new treatments or procedures are involved. However, the findings from the study could help improve future treatment strategies for colorectal cancer by offering better tools to predict genetic changes in the cancer.

Where is the study run from?

Jinhua Science and Technology Bureau (China)

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

The study will begin in March 2024 and is expected to end in July 2024.

Who is funding the study?
Jinhua Science and Technology Bureau (China)

Who is the main contact?
Hangping Wei, applewhp@163.com

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

Miss Hangping Wei

ORCID ID

<https://orcid.org/0000-0002-2904-7086>

Contact details

No. 60 West Wuning Road
Dongyang
China
322100
+86 13735632532
applewhp@163.com

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Hybrid model for predicting microsatellite instability in colorectal cancer using hematoxylin & eosin-stained images and clinical features

Acronym

MSI

Study objectives

Two deep learning methods (semi-supervised and fully-supervised) were used to extract features from pathological images. Subsequently, the pathomic signatures derived from these methods were integrated with clinical features to develop a hybrid model. The hybrid model was evaluated using an external validation cohort to calculate the area under the curve (AUC).

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 11/03/2024, The Institutional Ethical Review Board of Dongyang Hospital, affiliated with Wenzhou Medical University (No. 60 West Wuning Road, Dongyang, 322100, China; +86057986859051; dongxiaofang2022@163.com), ref: 2024-YX-039

Study design

Observational cross sectional study

Primary study design

Observational

Secondary study design

Cross sectional study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not applicable (retrospective study)

Health condition(s) or problem(s) studied

Colorectal cancer

Interventions

This study included two patient cohorts: The Cancer Genome Atlas cohort (TCGA set, n = 559), divided into training and internal validation subsets in a 7:3 ratio, and the Dongyang CRC cohort (Dongyang set), n = 123, which served as an external testing cohort. Two deep learning methods (semi-supervised and fully-supervised) were used to extract features from pathological images. Subsequently, the pathomic signatures derived from these methods were integrated with clinical features to develop a hybrid model. The hybrid model was evaluated using an external validation cohort to calculate the area under the curve (AUC).

Intervention Type

Other

Primary outcome measure

Tumor diagnosis and MSI status measured using patient records at a single time point

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

11/03/2024

Completion date

31/07/2024

Eligibility

Key inclusion criteria

1. Confirmed by pathological histology as a patient with colorectal cancer
2. Clear consciousness
3. Relevant tests have been conducted, including results of microsatellite and common gene mutation states (RAS, BRAF)
4. The patient voluntarily participates and signs an informed consent form

Participant type(s)

Patient

Age group

All

Sex

Both

Target number of participants

120

Total final enrolment

123

Key exclusion criteria

1. Patients with non primary colon cancer or a history of other organ malignancies at the same time
2. Results without microsatellite and common gene mutation states (RAS, BRAF)
3. Other patients with incomplete clinical data
4. Those with unclear pathological images

Date of first enrolment

12/03/2024

Date of final enrolment

01/07/2024

Locations

Countries of recruitment

China

Study participating centre
Jinhua Science and Technology Bureau
No. 60 West Wuning Road
Dongyang
China
322100

Sponsor information

Organisation
Jinhua Municipal Science and Technology Bureau

Sponsor details
Jinhua Science and Technology Bureau
Jinhua
China
322100
+86 57986859052
dongxiaofang2022@163.com

Sponsor type
Government

Website

-

ROR
<https://ror.org/0347g4065>

Funder(s)

Funder type
Government

Funder Name
Jinhua Science and Technology Bureau

Alternative Name(s)
Science and Technology Bureau of Jinhua City, Jinhua Municipal Science and Technology Bureau

Funding Body Type
Government organisation

Funding Body Subtype

Local government

Location

China

Results and Publications

Publication and dissemination plan

Plan to publish in peer-reviewed journals

Intention to publish date

31/07/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

Hangping Wei, applewhp@163.com

IPD sharing plan summary

Stored in non-publicly available repository, Available on request