

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

<b>Submission date</b> 17/09/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 22/09/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 18/09/2024	<b>Condition category</b> 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

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## Additional identifiers

## 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

**Study type(s)**

Diagnostic

**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(s)**

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

**Key secondary outcome(s)**

There are no secondary outcome measures

**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

**Healthy volunteers allowed**

No

**Age group**

All

**Sex**  
All

**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  
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322100

## **Sponsor information**

**Organisation**  
Jinhua Municipal Science and Technology Bureau

**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

**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.

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**IPD sharing plan summary**

Stored in non-publicly available repository, Available on request