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

Submission date
17/09/2024

Recruitment status
No longer recruiting

Registration date
22/09/2024

Overall study status
Completed

Last Edited
18/09/2024

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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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

Primary study design
Observational

Study design
Observational cross sectional study

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
China
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.
Hangping Wei, applewhp@163.com

IPD sharing plan summary
Stored in non-publicly available repository, Available on request