Study Protocol

Official Title: Exploration of Epigenetic Factors of Colorectal Adenoma in Korean

Short Title: Epigenetic Biomarker Study for Colorectal Adenoma

Version: 3.0

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Participating Institutions:

• CHA Bundang Medical Center (Seongnam, Korea)
• Eulji University, Department of Clinical Laboratory Science (Uijeongbu, Korea)

IRB Approval: Reviewed and approved by the Ministry of Health and Welfare–Designated Central Institutional Review Board for Human Biological Research.

ClinicalTrials.gov Identifier (NCT Number): [To be assigned]

1. Study Summary

This observational study explores epigenetic factors associated with colorectal adenoma in Korean adults undergoing colonoscopic polypectomy. The study aims to identify DNA methylation-based biomarkers that may predict colorectal cancer progression.

2. Methods

A total of 32 participants will be enrolled. Adenomatous and adjacent normal colorectal tissues will be collected during colonoscopic polypectomy. Stool samples will also be obtained for microbiome analysis. DNA will be extracted using Qiagen kits, followed by bisulfite conversion and quantitative methylation-specific PCR (qMSP) targeting SFRP2, TFPI2, SEPT9, and SDC2.

3. Statistical Analysis Plan

Methylation Index (MtI) and Percentage of Methylated Reference (PMR) will be calculated using the ΔΔCt method. ROC curve analysis will determine diagnostic accuracy (AUC, sensitivity, specificity). Correlations with clinical parameters such as age, BMI, smoking, and diet will be assessed.

4. Ethical Considerations

All participants will provide written informed consent before inclusion. Personal identifiers will be replaced with coded numbers to ensure confidentiality. Biospecimens will be stored at −80°C and discarded after analysis.

5. References

1. Korea Central Cancer Registry. 2021 Annual Report of Cancer Statistics in Korea. National Cancer Center, Ministry of Health and Welfare; 2023.
2. Oh T, et al. Genome-Wide Identification and Validation of a Novel Methylation Biomarker, SDC2, for Blood-Based Detection of Colorectal Cancer. J Mol Diagn. 2013;15(4):498–507.
3. Park SK, Baek HL, Yu J, et al. Is methylation analysis of SFRP2, TFPI2, NDRG4, and BMP3 promoters suitable for colorectal cancer screening in the Korean population? Intest Res. 2017;15(4):495–501.

Participant Information Sheet and Informed Consent Form

Official Title: Exploration of Epigenetic Factors of Colorectal Adenoma in Korean

Short Title: Epigenetic Biomarker Study for Colorectal Adenoma

Document Type: Participant Information Sheet and Informed Consent Form

Version: 2.1 (July 10, 2025)

Principal Investigator: KIM OneJoong, M.D.

Institution: CHA Bundang Medical Center, CHA University, Seongnam, Republic of Korea

IRB Approval: Ministry of Health and Welfare–Designated Central Institutional Review Board for Human Biological Research

ClinicalTrials.gov Identifier (NCT Number): [To be assigned]

Document Language: English translation of the original Korean IRB-approved version

1. Purpose of the Study

This study aims to identify methylated genetic factors that may serve as epigenetic markers associated with colorectal adenoma in Korean patients. By comparing the methylation status of specific genes between adenomatous tissue and adjacent normal mucosa, the study seeks to provide evidence for improving post-polypectomy surveillance intervals and colorectal cancer prevention strategies.

2. Participation Period, Procedures, and Methods

The total study period is expected to run until May 2027. Each participant will be involved for approximately one month. Participants undergoing colonoscopic polypectomy will have both adenomatous tissue and adjacent normal colorectal tissue (5 mm each) collected during the procedure. This additional normal tissue sampling is not part of standard treatment but poses minimal risk and no additional cost to participants. Stool samples will also be collected using a sterile stool collection kit provided at the outpatient clinic and delivered to the laboratory during the hospital visit. Samples will be rapidly frozen in liquid nitrogen and transported to the Eulji University Graduate Laboratory (Uijeongbu) for analysis. No medications or treatments outside of standard care will be administered, and participation will not affect regular medical care.

3. Number of Participants

A total of 32 participants, including a 20% expected dropout rate, will be enrolled.

4. Risks and Benefits

No drugs or additional tests beyond standard medical care will be performed. There are no direct personal benefits or compensations for participation. However, the study may provide social benefits by contributing to better understanding of methylation-based biomarkers and improving recommendations for follow-up colonoscopy intervals in patients with colorectal adenoma.

5. Compensation for Research-Related Injury

Polypectomy is a standard treatment for colorectal adenoma; therefore, there is no specific compensation for research participation. In case of any adverse event, emergency medical care will be provided according to standard hospital procedures.

6. Withdrawal of Consent

Participation in this study is entirely voluntary. Participants may withdraw consent at any time without penalty or loss of benefits to which they are otherwise entitled. Withdrawal will not affect ongoing clinical care or treatment decisions.

7. Contact for Questions or Concerns

For any questions about the study, risks, or research-related injuries, please contact:
Principal Investigator: Dr. Won Joong Kim (CHA Bundang Medical Center) – Tel: +82-31-780-5000
Co-Investigator: Prof. Seong Hee Hyun (Eulji University) – Tel: +82-31-951-3000

For questions about your rights as a research participant, contact the CHA IRB Office: +82-31-780-5302/5314.

8. Retention and Use of Personal Information

Personal information will be retained for up to 3 years after study completion, in accordance with the Bioethics and Safety Act. After the retention period, all data will be permanently destroyed in compliance with the Personal Information Protection Act.

9. Protection of Confidentiality

All personal data will be coded with participant identification numbers and initials. Names and addresses will be removed from study records. Only authorized research staff will have access to identifiable information. No information identifying participants will be disclosed in publications or presentations.

10. Personal and Sensitive Information Handling

Collected information includes participant ID, sex, date of birth, medical history, clinical findings, and genetic analysis results. Sensitive data such as health status or past medical history will be handled under strict confidentiality and used only for this study. Participants may refuse to provide personal information; however, doing so may preclude study participation.

11. Handling and Disposal of Biospecimens

Collected biospecimens will be processed according to institutional and legal standards. After data acquisition, specimens will be destroyed immediately. If a participant withdraws consent before anonymization, the corresponding specimens will be destroyed upon request.

12. Consent Statement

I have been fully informed about the nature, purpose, risks, and benefits of this study. I voluntarily agree to participate in this research and understand that I may withdraw at any time without penalty. I have received a copy of this consent form.

Participant Name: _____ Signature: _____ Date: _____

Legal Representative (if applicable): _____ Signature: _____ Date: _____

Investigator Signature: _____ Date: _____