

Study ID: 7-A/26

Title: European implementation study on simultaneous
screening for gastric and colorectal cancers

Acronym: EUGastScreen

Date: 18 July 2026

Informed consent

Introduction

Helicobacter pylori (*H. pylori*) is the primary risk factor for gastric cancer, and according to current guidelines (Maastricht VI/Florence consensus), it is recommended to detect and treat it. The *H. pylori* stool antigen test (SAT) detects specific *H. pylori* proteins in a stool sample, confirming active infection. In parallel, the Council of the European Union advises that all individuals aged 50 and older undergo a fecal immunochemical test (FIT), a non-invasive screening test that detects occult blood in stool, to evaluate increased risk of colorectal cancer (CRC).

The EUGastScreen is a European Union-funded multicenter research project led by the Institute of Clinical and Preventive Medicine at the University of Latvia. The study aims to combine these tests and explore gastric cancer screening strategies and possibilities within the existing organized colorectal cancer screening framework.

As you are over 50 years old and enrolling in the colorectal screening programme, we invite you to participate in the EUGastScreen study, which aims to improve cancer prevention and early detection.

Purpose

The purpose is to evaluate whether combining colorectal cancer screening with *H. pylori* testing is feasible and acceptable within the same screening process.

If you agree to participate

1. You will be asked to complete a short questionnaire.
2. In approximately 2 weeks, you will receive a package with 2 sampling kits for both screening tests.
3. You will be asked to collect a stool sample at home following the instructions provided and return the sample to the testing facility (laboratory) by self-service parcel using previously paid return shipping label already included in the package.
4. The returned samples will be analyzed. You will receive your test result by email from the laboratory.
 - **If both tests are negative**, your results will be available to you via email.
 - **If FIT is positive**, this does not necessarily indicate cancer. It means that further diagnostic tests are needed to determine the cause; therefore, you will be invited for a colonoscopy, as is standard in the national colorectal cancer screening program.
 - **If SAT is positive**, it indicates an active infection with *H.pylori*, and you will be offered treatment for the infection according to current medical guidelines. The medication will be provided free of charge within the study.
 - After completing treatment, you will be invited for a follow-up test (Urea breath test) to confirm that the infection has been cleared.
5. In certain situations (e.g., depending on the test results, symptoms, or medical history identified during the interview), you may be referred for an upper endoscopy (gastroscopy) for further evaluation.
6. The study team may contact you during the study to gather further information, including a phone questionnaire (about 20 minutes) if a test result is positive.
7. A trained medical staff member (physician assistant) from the study center, following the interview, will evaluate the indications and contraindications, and subsequently refer you for additional examinations and/or prescribe therapy.

All examinations and medications provided during the study will follow the regulations of the national healthcare system. Standard patient co-payments may apply where applicable.

Benefits

- The opportunity to be tested for both colorectal and stomach cancer at the same time
- The test can be completed at home; it is simple and convenient to receive and return
- The opportunity to contribute to research in cancer prevention and screening
- An investment in maintaining your own health

Possible risks

FIT and SAT tests are both non-invasive and safe. Risks are limited to slight inconvenience during sampling.

Confidentiality and data protection

Data collection will be conducted electronically using the digital platform Longenesis Engage. You can find out more about the functionality of the Platform in the [Privacy Policy](#) and [Terms & Conditions](#) of the Platform. Access to the platform will be secured through a safe authentication method, such as Smart-ID, eSignature, or another secure method.

During the study, data obtained through the digital platform will be stored and processed on cloud server infrastructure located within the European Union (EU) and/or the European Economic Area (EEA).

Your privacy and data security are protected in accordance with the EU General Data Protection Regulation (GDPR 2016/679) and the Personal Data Processing Law of Latvia. The legal basis for data processing is your informed consent, which you may withdraw at any time.

Data Controller is University of Latvia (Raiņa bulvāris 19, Rīga LV-1586)

Data Protection Officer: Jānis Uiska and Ginta Eglīte, Email: datu.specialisti@lu.lv

Data Processor is University of Latvia (Raiņa bulvāris 19, Rīga LV-1586) and SIA "Longenesis", Company Registration No. 40203211852, legal address: Zaubes Street 9A - 23, Riga, LV-1013, Latvia. E-mail: privacy@longenesis.com.

What data will be collected and processed?

- Contact data (email address, phone number, home address)
- Age, sex
- Personal ID / National ID number for secure linking of study data
- Information from the phone call questionnaire- health-related data (e.g., previous medical history, previously done endoscopies, gastric and colorectal cancer history in first-degree relatives, allergies, specific medication use)
- FIT and SAT results
- Additional diagnostic test results as part of the existing national colorectal cancer screening program and study-related follow-up test results (colonoscopy, upper endoscopy, breath test)

Who will process your data?

- The research team at the University of Latvia (national centers)
- Authorized employees of the Data Processor
- Latvian Postal Service (personal and contact data)
- Clinical data will be processed by health care institutions according to regular standard procedures

Only authorized personnel bound by confidentiality agreements will have access to identifiable data.

How will your data be protected and shared?

- Data from the testing facility will be automatically sent to the study data platform
- For scientific analysis, data will be used only in pseudonymized (coded) form.
- With your consent, your data may be securely linked to:
 - The National Health Service databases
 - The National Cancer Registry
 - Hospital records
- No information that could identify you will appear in any scientific report or publication.
- De-identified data may be shared with authorized EUGastScreen partners in other EU/EEA countries or stored in secure EU-based research repositories for verification or related analyses.
- No data will be transferred outside the EEA unless adequate protection (e.g., EU Standard Contractual Clauses) is in place.

How long will your data be stored?

Your data will be stored for approximately 10 years, after which it will be anonymized or securely destroyed.

How long will fecal test material be stored?

All the fecal material samples will be utilized after the test and will not be stored.

Your rights under GDPR

You have the right to:

- Access your personal data
- Request correction of inaccurate data
- Request erasure of your data
- Restrict or object to processing
- Withdraw consent at any time
- The right to submit a complaint to Data State Inspectorate of Latvia

To exercise these rights, contact the study team or the University of Latvia Data Protection Officer (67034881, datu.specialisti@lu.lv)

Voluntary participation

Participation in this research study is voluntary. You have the right to refuse to participate or to withdraw from the study at any time. Your refusal to participate or termination of participation will not have any consequences for the health services provided to you. You may withdraw from the study at any time. After your withdrawal, no new data will be collected from you. Your identifiable personal data will be deleted where possible. Data that have already been included in anonymised or pseudonymised research datasets or analyses may continue to be used for scientific analysis.

Ethics Committee approval

This study has been approved by the Riga East Clinical University Hospital Support Fund Medical and Biomedical Research Ethics Committee in the meeting held on 20.08.2026 (No.7-A/26).

Consent to participation in the European implementation study on simultaneous screening for gastric and colorectal cancers (EUGastScreen)

I confirm with my electronic signature that:

- 1) I am familiar with the information included in this document about the pilot study and understand the nature, purpose, conduct, risks and benefits of the study.
- 2) I had an opportunity to contact the research team for clarifications and to ask questions related to the donation of biological samples and the research process.
- 3) I understand that my participation in this study is voluntary and refusal to participate in the study or termination of participation will not lead to any adverse consequences.
- 4) I am informed about the purpose and scope of the processing of personal data.
- 5) I agree that during this pilot study, in accordance with the requirements of the laws and regulations, my personal data are collected, stored and processed, which are mentioned in the information about the study.
- 6) **I confirm that I have read and understood the information provided in the informed consent form and agree to participate in this research study.**

This document is prepared and valid in electronic form.