



Information Booklet for Study Participants

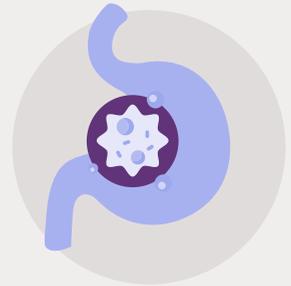
**STOMACH ASSESSMENT IN
SUBJECTS UNDERGOING COLONOSCOPY**

WHAT IS GASTRIC CANCER?

Gastric cancer (also known as stomach cancer) is a cancer of the stomach. The stomach is a J-shaped organ in the upper abdomen. It produces enzymes (substances that create chemical reactions) and acids (digestive juices). This mix of enzymes and digestive juices breaks down food.

When cells lining the stomach begin to behave abnormally, they can turn cancerous and grow out of control. This can prevent the stomach from functioning properly, causing uncomfortable symptoms and/or asymptomatic diseases. Too often these symptoms go overlooked, and the cancer is only diagnosed once it has spread.

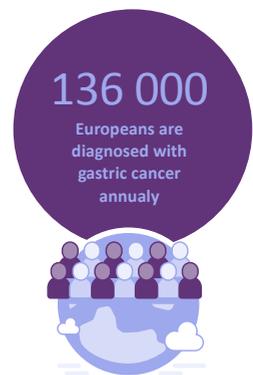
Gastric cancer begins in the cells of the stomach. Gastric cancer is the final step in several changes to the cells, most commonly triggered *H. pylori* infection¹ (please read on to find out more about *H. pylori*). Before gastric cancer develops, precancerous lesions can be present². These lesions are made up of stomach cells that have changes to them, which make them more likely to develop into cancer. Clinical surveillance of these lesions is crucial for preventing them from developing into gastric cancer.



HOW COMMON IS GASTRIC CANCER?

Gastric cancer is the fourth most common cancer in the world. Annually, an estimated 136 000 Europeans are diagnosed with gastric cancer, and ~97000 die from this aggressive disease³.

Once someone is diagnosed with gastric cancer, further examination and testing will be carried out to determine if the cancer has spread, and if yes, how far. This is called staging. The stage of cancer helps describe how serious it is and how best to treat it. The earlier the stage of the cancer at diagnosis, the better the chances of survival and successful treatment, which is why it is important to diagnose it at an early stage if possible.



References:

1. Schistosomes, liver flukes and Helicobacter pylori. IARC Working Group on the Evaluation of Carcinogenic Risks to Humans. Lyon, 7-14 June 1994. *IARC Monogr Eval Carcinog Risks Hum* **61**, 1 (1994).
2. Rugge, M., Capelle, L. G., Cappellesso, R., Nitti, D. & Kuipers, E. J. Precancerous lesions in the stomach: From biology to Clinical Patient Management. *Best Practice & Research Clinical Gastroenterology* **27**, 205–223 (2013).
3. Global Cancer Observatory: Cancer Today. Lyon, France: International Agency for Research on Cancer. Available from: <https://gco.iarc.fr/today>, accessed 10/07/2022.

WHO IS AT RISK OF DEVELOPING GASTRIC CANCER?

There are several known factors that can increase your risk of getting gastric cancer, these include⁴:



INFECTION WITH *HELICOBACTER PYLORI* (*H. PYLORI*): A common bacterial infection, that can increase your risk of developing gastric cancer if left untreated¹.



GENDER: Men are around twice as likely to get gastric cancer than women⁵.



AGE: There is a sharp increase in gastric cancer rates in people over age 50. Most people diagnosed with gastric cancer are between their late 60s and 80s⁵.



SMOKING: Those who smoke have around double the risk of gastric cancer compared with those who don't^{5,6}.



WEIGHT: Being overweight or obese is associated with an increased risk of developing gastric cancer⁵.



DIET: There is an increased risk of gastric cancer for those with diets high in salted meat, stewed meat, and smoked or pickled foods^{5,6}.



INDUSTRIAL CHEMICAL EXPOSURE: Individuals exposed to dusty and high-temperature environments in their daily life have an increased risk of several forms of cancer, including gastric cancer⁵.



FAMILY HISTORY OF GASTRIC CANCER: People with family members who have had gastric cancer are more likely to develop it themselves as well⁵.

WHAT CAN I DO TO REDUCE MY RISK OF DEVELOPING GASTRIC CANCER?

Several of the risk factors listed above are related to lifestyle. Making certain changes can lower your risk of developing gastric cancer.



GET TESTED FOR *H. PYLORI*:
H. pylori is a type of bacterium that infects lining of the stomach.

H. pylori infection is the most significant risk factor for gastric cancer¹.

Getting tested for *H. pylori* and, if the bacteria are present, having the infection treated can greatly reduce your risk of developing gastric cancer.



STOP SMOKING:
Tobacco increases the risk of gastric cancer and many other diseases.

Cigarette smoke contains more than **7000 toxic compounds**, out of which at least 70 of which have been proven to be carcinogenic⁷. When you smoke, you expose your body to all these compounds that have a detrimental effect on your digestive system, among several other parts of your body.



REDUCE SALT INTAKE:
Protect your stomach lining by limiting the amount of **salty** and **smoked foods** you eat^{5,6}.

You can consult your healthcare provider for information on how to reduce risk factors related to lifestyle choices.



References:

1. Schistosomes, liver flukes and Helicobacter pylori. IARC Working Group on the Evaluation of Carcinogenic Risks to Humans. Lyon, 7-14 June 1994. *IARC Monogr Eval Carcinog Risks Hum* **61**, 1 (1994).
4. Stomach Cancer: Risk Factors | Cancer.Net. <https://www.cancer.net/cancer-types/stomach-cancer/risk-factors>.
5. Zali, H., Rezaei-Tavirani, M. & Azodi, M. Gastric cancer: prevention, risk factors and treatment. *Gastroenterol Hepatol Bed Bench* **4**, 175 (2011).
6. Rawla, P. & Barsouk, A. Epidemiology of gastric cancer: global trends, risk factors and prevention. *Prz Gastroenterol* **14**, 26 (2019).
7. Harmful Chemicals in Tobacco Products | American Cancer Society. <https://www.cancer.org/cancer/risk-prevention/tobacco/carcinogens-found-in-tobacco-products.html>

WHAT ARE THE SYMPTOMS OF GASTRIC CANCER?

The progression of gastric cancer usually takes several years, and symptoms can be mild, sometimes even unnoticeable, and easily confused with general digestive problems, viruses, or ulcers, until the disease has advanced. This is why it is important that you consult your healthcare provider if you have persistent symptoms that resemble the ones described below.

When symptoms do appear, they often affect your digestion and can include:

	Indigestion, such as frequent burping		Nausea and vomiting, particularly vomiting up solid food shortly after eating
	Persistent stomach pain		Bloating of the stomach after meals.

Symptoms of more advanced gastric cancer can include:

	Blood in your stools, or black stools		Loss of appetite or feeling full after eating small amounts		Losing significant weight without trying – significant weight is defined as losing more than 10% of your body weight.
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WHY SHOULD I TAKE PART IN GASTRIC CANCER PREVENTION?

Gastric cancer treatment is most likely to be successful if the cancer is detected in its early stage, making it easier to treat, and resulting in significantly improved outcomes.

Unfortunately, most gastric cancers are found at later stages when symptoms are already present. In these cases, a cure is less likely. Hence, taking part in gastric cancer screening, even if you are not experiencing any symptoms, can prove to be lifesaving.

However, in most countries, there is no screening for gastric cancer. Therefore, it is important that individuals at high-risk are aware of the symptoms and can recognise even the initial symptoms, in order to increase their chances to be diagnosed at an early stage. Anyone with a family history of the disease or other risk factors should speak with their doctor about getting screened for gastric cancer.



HOW IS GASTRIC CANCER TESTING RISK CARRIED OUT?

There are several methods that are used to test for gastric cancer. Since there is no standardised screening method or programme for gastric cancer, generally the doctor decides based on the patient's medical history, symptoms, and other factors what method to use to screen for gastric cancer.

The following methods are most common⁸:



UPPER ENDOSCOPY
(WITH OR WITHOUT BIOPSY)



PEPSINOGEN TEST FOR
ATROPHIC GASTRITIS



IMAGING
TESTS



UREA BREATH TEST
FOR *H. PYLORI*

WHAT IS THE TOGAS PROJECT?



TOGAS stands for TOWARDS GAstric cancer Screening implementation in the European Union. Currently, there is no effective screening method widely available in Europe for the early detection of gastric cancer. The general objective of TOGAS is to provide the missing evidence-based knowledge that can be used to design, plan, and implement appropriate gastric cancer prevention and screening across the EU.

For more information on the TOGAS project, please visit the TOGAS website: <https://www.togas.lu.lv/>

TOGAS comprises three pilot studies (a pilot study is an initial study that is done to help inform and improve the design, process, and preparedness of a full-scale study) across Europe.

You are being invited
to take part in pilot study **2**.

WHAT IS THE AIM OF THE STUDY?

This study is part of the TOGAS project, and it aims to test the feasibility of simultaneous stomach assessment through upper endoscopy in people undergoing colonoscopy.

Please read on to learn more.



References:

8. Tests for Stomach Cancer | Diagnosis of Stomach Cancer | American Cancer Society. (n.d.). Retrieved July 20, 2023, from <https://www.cancer.org/cancer/types/stomach-cancer/detection-diagnosis-staging/how-diagnosed>

WHY SHOULD I TAKE PART IN STUDY?

Your participation in this study will aid the success of the TOGAS project, meaning that you can contribute missing knowledge that can be used to design, plan, and implement appropriate gastric cancer prevention and screening across the EU. Furthermore, your participation is also beneficial to your health, as you will learn if you are at risk of or suffer from stomach cancer.

WHAT IS COLONOSCOPY?

Colonoscopy means the examination of the inside of your large intestine (colon and rectum). It is used to diagnose gastrointestinal diseases, such as inflammatory bowel disease and colorectal cancer. It is a type of endoscopy, meaning that it uses an endoscope (a flexible tube with a lighted camera on the end, which is inserted into your body). During a colonoscopy, the colonoscope (a type of endoscope) passes through your anus and rectum into your colon, while sending pictures of the inside of your large intestines to a computer. Colonoscopy is most commonly carried out under sedation.

WHAT IS UPPER ENDOSCOPY?

Upper endoscopy, which is also referred to as gastro-endoscopy, endoscopy, gastroscopy, or as oesophago-gastro-duodenoscopy (OGD), means the examination of the upper part of the gut, which includes the oesophagus (food pipe), stomach and the first part of your small bowel (duodenum). For this, a gastroscope (another type of endoscope) is used, meaning that similarly to colonoscopy, a flexible tube with a lighted camera on the end, is inserted into your body. In this case, it passes through your mouth and oesophagus, into your stomach, while sending pictures of the inside of your oesophagus and stomach to a computer. Upper endoscopy is also most commonly carried out under sedation and no pain is experienced during the procedure.

WHAT IS A BIOPSY?

During this study, a biopsy will also be performed to evaluate the health status of your stomach. A biopsy is a procedure to remove a small amount of tissue or a sample of cells from your body, which can then be tested in a laboratory. Generally speaking, out of all available tests, only a biopsy can positively confirm the presence of cancer cells⁹.

WHAT IS A FIT?

You may have been referred for colonoscopy due to a positive FIT result. FIT stands for Faecal Immunochemical Test. FIT detects hidden blood in the stool, coming from the intestines, which can be an early sign of colorectal cancer. A FIT test requires you to collect a sample of your stool and send it in for analysis. A test kit is provided for this, and the stool sample can be collected at home. People with a positive result (meaning that there were traces of blood in your stool) are referred for colonoscopy.

WHAT IS A PEPSINOGEN TEST?

During this study, a pepsinogen test may also be carried out. Pepsinogen I and II are substances made by cells in the stomach. As part of this study, the levels of pepsinogen in your blood (serum pepsinogen levels) may be measured. This can tell your doctor a lot about the health of your stomach.

References:

1. Biopsy. Cancer.Net (2022). Available at: <https://www.cancer.net/navigating-cancer-care/diagnosing-cancer/tests-and-procedures/biopsy>. (Accessed: 26th July 2023)

WHY AM I BEING REFERRED FOR COLONOSCOPY COMBINED WITH UPPER ENDOSCOPY?

Colonoscopy and upper endoscopy are commonly performed during the same sedation time, yet carrying out upper endoscopy in combination with colonoscopy is not a procedure implemented in national screening programs. However, upper endoscopy, which isn't routinely performed on patients coming for a screening colonoscopy outside of this study, will provide new data on the relevant prevalence of precancerous lesions and *H.pylori* infection, as well as on the accuracy of pepsinogen testing. Furthermore, upper endoscopy is a fast procedure and does not carry additional risk(s) compared to only colonoscopy.



WHAT WILL THE FINDINGS TELL MY DOCTOR AND ME?

The findings provide indications on the general health of your digestive system. It will also be possible to determine or exclude the presence of *H. pylori* infection, precancerous lesions, or colorectal or gastric cancer.

WHAT IS *H. PYLORI*?

During this study, you will be offered testing for *H. pylori* infection. *Helicobacter pylori* (*H. pylori*) is a type of bacterium that infects the stomach. *H. pylori* commonly causes peptic ulcers, which are sores of the stomach (gastric ulcer) or the duodenum (duodenal ulcer).

H. pylori infection is present in half the people in the world or more. However, in most people, the infection is asymptomatic (meaning that you don't feel sick from it), so many people may not realise they have it.

***H. pylori* infection can cause several complications, including:**



Inflammation of the stomach lining: *H. pylori* infection can affect the stomach, which can lead to irritation and swelling (gastritis).



Ulcers: *H. pylori* can damage the protective lining of the stomach and small intestine. Consequently, stomach acid can create an ulcer (an open sore). Up to 20% of people with *H. pylori* can develop an ulcer¹⁰.



Gastric cancer: *H. pylori* infection is a significant risk factor for stomach cancer.

This is why it is important to have your *H. pylori* infection treated if you find out that you have it¹⁰.

As part of the TOGAS project, you will be asked to fill out a questionnaire designed to assess your experience throughout the study, you can access this questionnaire via this link or via the following QR code:

<https://digestivecancers.limesurvey.net/141453?lang=en>



References:

10. Mallertheiner, P. et al. Management of *Helicobacter pylori* infection: the Maastricht VI/Florence consensus report. *Gut* 0, 1–39 (20



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