

INFORMATION PROTOCOL AND REQUEST FOR CONSENT FOR ESOPHAGOGASTRODUODENOSCOPY

Note: In cases of confirmed or suspected allergy to LATEX, please book the colonoscopy for 8.00 am (the first test of the day).

Esophagogastroduodenoscopy (EGD or OGD), gastroscopy or endoscopy in common parlance, is a test to examine the lining of the upper digestive tract (the oesophagus, stomach and duodenum) using a gastroscope, also known generically as an endoscope. This is an instrument consisting of a flexible tube with a diameter of less than 1 cm, fitted with a small camera on the tip that sends the images of the lining of the digestive tract to a monitor. The stomach is slightly expanded using air in order to gain a more accurate picture. If the doctor carrying out the test considers it necessary, biopsies (small samples of mucosa) may be taken during the procedure, using small pincers. These will be sent to the laboratory for examination under a microscope (histological examination).

BEFORE THE TEST

After removing any dentures and other personal effects, you will be asked to lie on a bed on your left side. A blood pressure monitor will be fitted to your arm, along with a pulse oximeter to monitor your pulse rate and blood oxygenation. A local anaesthetic will then be sprayed into your mouth to numb your throat and prevent you from gagging. A mouth guard will be inserted between your teeth to protect the endoscope.

SEDATION

We normally perform gastroscopies on patients who are sedated and received analgesics (unless you specifically request not to) in order to considerably reduce discomfort and make the procedure less stressful. Sedation not only improves the patient's ability to cooperate, it also offers a better guarantee that the endoscopic procedure will be carried out more easily and accurately. More information about sedation is provided on the informed consent form that will be given to you when you book the procedure. In order to have sedation you will need to be accompanied to the hospital by an adult. ***You will not be able to carry out activities which require you to be completely physically and mentally fit (such as driving) for the following 24 hours.***

DIAGNOSTIC ALTERNATIVES OF SIMILAR EFFICACY AND THE GROUNDS FOR HAVING THE TEST

The diagnostic alternative to the oesophagogastroduodenoscopy is a double-contrast X-ray examination. However, this test does not always provide all the answers needed, and often needs to be followed up by an endoscopy to confirm diagnosis or to take biopsies (or carry out more complex procedures) on definite lesions.

Flat or very fine mucosal lesions do not show up on an x-ray. The EGD also allows biopsies (mucosal samples) to be taken for histological examination.

THINGS TO AVOID OR TREATMENT TO BE CARRIED OUT BEFORE THE TEST

In order to gain an optimal view of the stomach, you must not eat or drink anything except for water from midnight before the day of the test. You may take drugs, if necessary, but not anti-acid preparations (such as Maalox) or activated carbon. You must also tell the medical staff if you have already had x-rays or other endoscopic tests (in this case, please bring all the documentation with you) or if you have had any allergic reactions to drugs on other occasions. In special cases (e.g. patients with valve defects or heart valve prostheses) a course of antibiotics may be prescribed, When booking the exam, you should also mention any anti-coagulant treatment you are taking, as this would make biopsies or other procedures possibly causing bleeding contraindicated. In such cases the doctor will advise the course of action.

THE EXPECTED BENEFITS OF THE TEST

The EGD is an accurate test, and allows the diagnosis of diseases of the upper digestive tract, including with the support of mucosal samples, if necessary, which are then examined by the anatomical pathologist. This would allow the correct treatment to be prescribed for the pathology found. The test also allows treatment to be carried out rather than having to undergo traditional treatment (haemostasis of bleeding lesions, removal of polyps, removal of foreign bodies, dilation of narrowed sections, etc.). The doctor will explain in detail the risks and benefits of carrying out an endoscopy. There is a small risk of diagnostic error. Literature shows that the test is not 100% accurate. In other words, changes that may be benign may be considered to be more serious, or potentially malignant pathologies may be seen as less serious. The literature does not currently provide unequivocal data about the extent of this risk.

DISCOMFORT, SIDE EFFECTS AND THE INEVITABLE CONSEQUENCES OF THE TEST

Sedation significantly reduces the discomfort of the procedure. Because of the sedation you may have no memory of the test. If you decide to have the test without sedation, you may feel slight discomfort in your throat owing to the passage of the endoscope, abdominal distension and retching during the examination.

This discomfort can be partly controlled by continuing to breathe normally and not swallowing. Sometimes the discomfort may be greater. The biopsy is a painless procedure. After the test is finished, your throat could still be anaesthetised and feel swollen for a short period of time. You will be able to have food and liquids once the feeling has returned to your throat (gag reflex), normally after about 30 minutes.

You will be given more specific information and the results of the endoscopy will be explained and described to you in detail. On rare occasions, a continuing feeling of throat discomfort may be experienced which normally passes after a few hours.

POSSIBLE RISKS AND COMPLICATIONS OF THE PROCEDURE RECOMMENDED

A diagnostic EGD is a safe procedure, but as it uses instruments that are introduced inside the body it may lead to complications such as perforation, haemorrhage and cardio-respiratory problems. However, such complications are very rare. Perforation happens in around 1 in 10,000 tests carried out, haemorrhage in 1 in 3,000 cases and cardio-respiratory problems in 1 in 1,000 cases. In addition to the more common complications, there are other more or less serious complications that are absolutely impossible to predict and may also involve organs other than the digestive tract. Normally, they are linked to the patient's condition. The risk of infection transmission (from bacteria, viruses or fungi) is entirely negligible, as the instrument is first carefully hand-washed, decontaminated and washed using special automatic washing machines to ensure a high level of disinfection. All the accessories used (biopsy forceps, polypectomy devices, needles for injections, etc.) are disposable or are sterilised like theatre instruments.

THE POSSIBILITY OF CHANGING OF EXTENDING THE PROCEDURE ONCE PLANNED AND AUTHORISED IN THE CASE OF UNEXPECTED AND CURRENTLY DIFFICULT TO PREDICT SITUATIONS

In the majority of cases, the complications reported are resolved after a period of observation in the outpatients' department or a short spell in hospital, but in some cases they may require emergency surgery and very rarely they may be life-threatening.

EXPECTED CONSEQUENCES OF NOT HAVING THE PROCEDURE

The EGD is a fundamental test for many diseases of the upper digestive tract. Therefore, if the test is considered indispensable, not having it could make it difficult or impossible to diagnose some diseases. Not having it could mean having inappropriate treatment, but especially not recognising certainly progressive diseases and tumours that could be treated by endoscopic or surgical procedures.

I, the undersigned confirm that I have received exhaustive answers from Dr. _____ including to all the questions and clarifications I spontaneously asked, and that I am fully conscious, aware and free to make choices about my person.

Patient's signature

Signature of parent or legal guardian

Signature of interpreter who states that he/she has translated the information sheet

Doctor's signature

Date

INFORMED CONSENT

Having understood the situation that has been explained to me, I hereby

CONSENT **DO NOT CONSENT**

by my own, spontaneous, informed will, to a:

ESOPHAGOGASTROSCOPY + BIOPSY IF NECESSARY

Personal data will be handled in full compliance with my privacy (Italian Law 196/2003).

Patient's signature

Signature of parent or legal guardian

Signature of interpreter who states that he/she has translated the information sheet

Doctor's signature

Date

Note: Patients that have given their consent are free to withdraw it and refuse to have the test at any time.

**INFORMATION PROTOCOL AND REQUEST FOR CONSENT
TO SEDATION AND ANALGESIA FOR THE ENDOSCOPY**

Date _____

Name and surname:

Test:

PATIENT INFORMATION

What is sedation/analgesia?

Dear Patient, the test that has been requested for you could cause discomfort and, in some cases, pain. In order to reduce discomfort and make the procedure more comfortable for you, we suggest you receive some drugs intravenously – opiates (to remove pain and/or retching) and benzodiazepine to make you a little sleepy, calm anxiety and make sure you don't have a bad memory of the procedure you have decided to undergo. While under sedation and analgesics, you will still be able to breathe on your own, respond to touch and to verbal instructions.

How am I given it?

The drugs most commonly used for sedation and analgesia are Diazepam and Midazolam (from the benzodiazepine family) and the opiates Alfentanil, Fentanyl and Pethidine, administered intravenously in gradually increased small doses until the desired level of sedation is reached. The choice of drugs is made by the endoscopy doctor based on an assessment of your general clinical conditions as well as the type and expected duration of the procedure. Topical anaesthetic of the oral cavity and pharynx may also be carried out using a spray anaesthetic.

Sedation and analgesia are carried out with constant monitoring of the patient's cardio-respiratory functions.

Why is it carried out?

The purpose of sedation during an endoscopy is to considerably reduce discomfort for the patient and make the examination less stressful. Sedation not only improves the patient's ability to cooperate (especially if they are frightened by the procedure), it also offers a better guarantee that the endoscopic procedure will be carried out more easily and accurately.

What are the complications?

Conscious sedation, like any medical procedure, may cause complications such as:

- nausea and vomiting – relatively more frequently (5%-7% of cases)
- respiratory depression, apnoea and in extremely rare cases, cardio-respiratory arrest
- muscular contractions
- changes in blood pressure and heart rate
- an allergic reaction with rare cases of bronchospasm
- euphoria
- possibility of failure to sedate – extremely rare – owing to individual resistance



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The onset of such complications may be controlled and treated through the constant monitoring of vital functions and with mechanical medical aids and antidotes to hand. In extremely rare cases they may lead to an unfortunate outcome.

In rare cases there may be local complications in the sites where drugs are injected, such as pain, bleeding or thrombophlebitis, adverse reactions to plasters.

Patients must not drive vehicles or use potentially dangerous machinery, carry out difficult work or take legal decisions for 24 hours after the endoscopy and may only leave the outpatient's clinic if accompanied.

What is the alternative?

To carry out the endoscopy without sedation or with local oropharyngeal anaesthesia only.

However, this will require greater cooperation on your part in order to be able to tolerate the procedure, and may further reduce the diagnostic reliability of the test.

Informed consent to sedation/analgesia

I, the undersigned

declare that I have been informed by Dr.

clearly and comprehensibly, about the possibility of undergoing the proposed endoscopic examination under sedation.

I declare that I have carefully read and have received explanations about the information about sedation provided and therefore that I have clearly understood its application and method of execution, that I am fully aware of the objectives, benefits, failures and any risks and complications relating to the administration of the drugs used.

I have also been informed about the possible alternative of having the examination without sedation, which I choose to reject.

The information provided has been exhaustive, fully comprehensive and clearly understood and I therefore give my informed, conscious consent, to receive conscious sedation/analgesia

Date

Patient's signature

Signature of parent and/or guardian and/or interpreter

Doctor's signature





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PATIENT'S MEDICAL HISTORY

SURNAME and NAME: _____

Dear Patient,

Please fill in all the items on this form and give it to the healthcare personnel at the Endoscopy Service. Your cooperation helps us to help you.

1) Do you suffer from heart disease or very high blood pressure?

YES NO

2) Do you suffer from neurological problems?

YES NO

3) Have you suffered from viral hepatitis, or are you suffering from any infections at the moment?

YES NO DON'T KNOW

4) Are you HIV-positive?

YES NO DON'T KNOW

5) Do you suffer from metabolic problems such as hypo/hyper-thyroidism or diabetes?

YES NO

6) Do you suffer from muscular pathologies?

YES NO

7) Do you take anticoagulant drugs?

YES NO

8) Are you allergic to any substances?

YES NO Which? _____

9) Which drugs do you take regularly?

Date

Patient's signature

