CONSENT INFORMATION FORM: COLONOSCOPY

Unit of Gastroenterology ASL 5



Dear Lady, Dear Sir,

A colonoscopy is a procedure, where the doctor uses an instrument called a colonoscope to look at the inside lining of your large bowel. This is done to see if there are any polyps, cancers or disease in your bowel. A colonoscope is a long, thin, flexible tube with a small camera and light attached which allows the doctor to see the pictures of the inside of your bowel on a video screen. The scope bends, so that the doctor can move it around the curves of your colon. The scope also blows gas (carbonic dioxide) into your bowel, so that the doctor can see better. As a result, you might feel some pressure, bloating or cramping during the procedure. This instrument can also be used to remove or burn growths or polyps and/or to take biopsies. Polyps are benign tumor; they should be removed before they transform themselves in malignant lesions. You will lie on your side or back while your doctor slowly passes the colonoscope along your large bowel to look at the bowel lining. You should plan on two to three hours for waiting, preparation and recovery. The procedure itself usually takes anywhere from 15 to 60 minutes. We strongly suggest undergoing colonoscopy with sedation, because the procedure may be otherwise unpleasant or painful. Sedation is the use of drugs that have a analgesic-effect and give you a 'sleep-like' feeling: an opioid (a synthetic derivative of opium) and a benzodiazepine are usually used. Before the procedure begins, the nurse will put a drip into a vein in your forearm, or hand. This is where the sedation is injected. Your blood pressure, respirations, pulse, and oxygen level will be monitored by a nurse throughout the procedure. Sedation will affect your judgment for about 24 hours. For your own safety and in some cases legally: do not drive any type of car, bike or other vehicle. You must be taken home by a responsible adult person: do not operate machinery; do not make important decisions or sign a legal document; do not drink alcohol, take other mind-altering substances, or smoke. They may react with the sedation drugs.

If your bowel is not very clean, the doctor may miss important lesion: a preparation is usually made up of drinking a large amount of a special cleansing drink. Details about the preparation are reported in a companion document, available on http://www.asl5.liguria.it/Home/SpecialitaServizi/Reparto.aspx?rid=32.

We suggest you, to bring all your prescribed drugs, those drugs you buy over the counter and show the gastroenterologist what you are taking. Tell the doctor about any allergies or side effects, you may have. If you take drugs for diabetes, get some advice from your General Practitioner about any modification of dosage and time schedule. If you take Warfarin (Coumadin), you can assume it, as usual, but you will be requested to show the gastroenterologist a recent determination of International Normalized Ratio (I.N.R.). If you take Eliquis, Lixiana, Pradaxa, or Xarelto, skip the morning dose. If you are taking a drug, that is used to thin your blood and a polyp (diameter ≥ 1 cm) will be found during colonoscopy, the polyp will not be removed; the colonoscopy will be rescheduled after stopping the drug. Otherwise, it will be never suggest stopping ASA, also when polypectomy is planned.

Colonoscopy is generally safe, but there are risks with the procedure. The personnel are trained to recognize and immediately treat any adverse event. Common adverse events include the following: mild pain and discomfort in the abdomen (This usually settles with walking, and moving around to get rid of the trapped gas); nausea, vomiting, faintness or headache, especially when you start to move around (these effects may be due to sedation); pain, redness or bruising at the sedation injection site; muscle aches; allergy to medications given at time of the procedure. Uncommon risks include:

- About 1 person in every 1,000 will accidentally get a hole (perforation) to the bowel causing leakage of bowel contents into the abdomen. Surgery may be needed to repair the hole. Damage to surrounding organs (for instance: spleen injury) is reported, but very rare. Risk is slightly higher, when a polyps is removed.
- About 1 person in every 100 will experience a significant bleed from the bowel where a polyp was removed, or where biopsies are done. Further colonoscopy, a blood transfusion or an operation may be necessary. If bleeding happens during colonoscopy, the gastroenterologist can stop it injecting drugs, or sealing off bleeding vessels, by small clips or by heat treatment.
- Not being able to see the entire bowel. This can happen if your bowel is not completely clean or the colonoscope could not be passed to the end of your large bowel. The gastroenterologist will be very meticulous in examining the entire lining of your bowel; nevertheless, polyps or other lesions may be occasionally missed.
- Heart and lung problems such as heart attack, or vomit in the lungs, causing pneumonia. Infection occasionally may happen.
- An existing medical condition that you may already have getting worse.
- Severe allergy to medications given, at the time of the procedure.

Your doctor suggested colonoscopy, because he thinks this examination is useful to give you the correct treatment, or as a screening test to prevent colorectal cancer. If you don't have the procedure, your symptoms may become worse and the doctor will not be able to give you the correct treatment without knowing the cause of your problems. Instead of colonoscopy, you can have a CT colonoscopy: this a radiological examination, that grants an accurate visualization of any growth inside the colonic lumen. The major drawback of CT colonoscopy is the fact it does not allow biopsies and removal of polyps; furthermore, redness or inflammation of the mucosal lining of the bowel can't be seen. Thus, optical colonoscopy is sometimes required after CT colonoscopy. Fecal occult blood test (FIT) may be an alternative to colonoscopy as a screening test: get advice about it, from your

General Practitioner, or from a gastroenterologist. The ASL 5 invites every two years all people aged 50-69 years to join the regional, FIT-based screening program. ASL 5 will not invite you to join the regional screening program, during the first 5 years after the present colonoscopy.

After colonoscopy, notify the hospital Emergency Department straight away if you have; severe ongoing abdominal pain; black tarry motions or bleeding from the back passage (more than ½ cup of blood); a fever; sharp chest or throat pain; have redness, tenderness or swelling for more than 48 hours where you had the injection for sedation.

DECLARATION OF CONSENT (in accordance with the Law 219/2017)

I hereby,
or I, delegate
Signature of the patients, who delegates

Date
or I, legal representative
In the case of a subject without decision-making autonomy, the

documentation will be enclosed showing the source of the

decision-making authority.

I acknowledge that the doctor has fully explained:

- my medical condition and its prognosis
- what is the colonoscopy, its benefits and risks, including the risks of sedation.
- the other diagnostic options and their benefit and risks.
- The risks of not having the procedure.

I acknowledge also that:

- I was able to ask questions and raise concerns with the doctor. My questions and concerns have been discussed and answered to my satisfaction.
- I have fully understood the information the doctor gave to me.
- I had time enough to mature the decision to consent.
- if immediate life-threatening events, or other unpredictable events happen during the procedure, the proposed procedure may be changed and the necessary treatments may be immediately implemented.
- I understand I have the right to change my mind at any time.

PlaceDate	
I CONSENT (Signature)	
I DO NOT CONSENT (Signature)	
I consent to colonoscopy, but I do not consent to sedation (Signature)	
The doctor, who informed the Patient (Signature)	. (Date)
The doctor, who performed the procedure (Signature)	(Date)

