

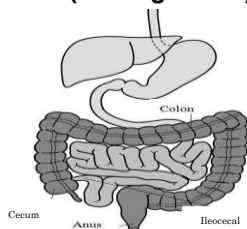
Colonoscopy

The following guide to the colonoscopy explains the purpose, flow, and risks of the procedure. After reading it carefully, please sign the attached consent form.

*Please note that in cases in which the procedure and/or treatment cannot be performed safely at our clinic, we will refer you to an appropriate hospital.

1 Purpose of the colonoscopy

The purpose of the colonoscopy procedure is to evaluate for diseases (polyps, cancer, inflammation, etc.) in the large intestine. During the procedure, an endoscope will be introduced through the anus and the entire large intestine will be observed. (See Fig below)



2 Overview of the procedure

1) Bowel preparation

Bowel preparation (emptying the contents of the colon) is necessary for a successful colonoscopy. If there is stool remaining in the colon, observation may be insufficient and lesions may be missed. On the day before the procedure, you will eat a special meal (Clearthrough meal) and take laxative medications. On the day of the procedure, you will drink the bowel irrigation agent. You may be instructed to take additional laxatives depending on your bowel movements.

2) Intravenous sedation (if applicable)

Sedatives are used to reduce anxiety and discomfort during examinations. However, the use of sedatives comes with certain considerations, such as age restrictions, post-examination activity limitations (* see below), drowsiness, lightheadedness, temporary amnesia (forgetfulness) and risks of complications. While some individuals may fall asleep under sedation, the effects vary from person to person, and on certain days, depending on one's condition, the sedation may leave you feeling "fully conscious" or feel "less effective than before." We kindly ask for your understanding in this matter.

The sedatives used at our clinic are from the benzodiazepine class, which is generally widely used. Please be aware that, although rare, some individuals may find the sedative effects entirely ineffective or insufficient due to their physiology.

3) Insertion of the scope

The scope will be inserted through the anus until it reaches the cecum. If you are at risk of having a lot of pain with the scope insertion (such as patients who have adhesions from prior abdominal surgery), we recommend using sedation.

4) Observation of the colon

Once the scope reaches the cecum, air will be inserted to expand the colon for observation. Therefore, you may experience abdominal bloating during the procedure.

5) Biopsy and polypectomy (Polyp removal)

Biopsy

If abnormalities are found or suspected, a biopsy may be performed, in which a small fragment of tissue is obtained and evaluated under a microscope. This enables us to diagnose the type of lesion, such as a tumor or inflammation. After biopsy, minor bleeding may occur, but typically it resolves on its own. However, in rare cases persistent bleeding or profuse bleeding may occur after biopsy.

Polypectomy

If a polyp is found, a procedure called polypectomy may be performed to remove the polyp. With some colon polyps, a small part of the polyp may be cancerous. Therefore, if only a part of the polyp is biopsied, a cancer may be missed. In addition, benign polyps may turn into cancer in the future. Thus, the entire polyp must be removed for more accurate diagnosis and treatment.

Our clinic does not have inpatient services. Therefore, treatment will be performed only for lesions that can be safely treated on an outpatient basis, as determined by the doctor performing the colonoscopy. The procedure will be completed after confirming that bleeding has stopped after polypectomy. However, in rare cases, rebleeding may occur, even a few days after the procedure.

*Please note that we cannot perform polypectomy using electric currents for patients with metal accessories, blood glucose monitors, implanted medical devices such as pacemakers, or tattoos covering a large area (if the grounding pad cannot be placed). Patients with dental bridges, dental implants, artificial joints, metal inserted after bone fractures, and small tattoos can undergo polypectomy.

3 Preparation before the colonoscopy

1) Diet

* Please refer to the separate instruction form.

2) Regular medication

① Medications for hypertension, epilepsy, psychiatric conditions, or arrhythmias

Please take your usual medications on the morning of the procedure.

*If you take other medications, please contact us to determine which medications to take prior to the procedure.

② Medications for diabetes (blood sugar lowering agents, including injections)

Please skip the usual morning and lunch doses of both oral medications and injections.

③ Blood thinning medications

*Please refer to the separate Instructions on Medication Discontinuation

To reduce risk of bleeding

If you are currently taking blood thinners or have liver disorders or blood disorders, you must consult with your primary doctor before the procedure to determine whether you can undergo treatment (polypectomy) and/or biopsy during the colonoscopy.

Discontinuation of blood thinners may increase the risk of blood clots, which may have severe consequences. In general, you **do not need to discontinue blood thinners** prior to the colonoscopy. We will perform the procedure and treatment safely as determined by the doctor performing the colonoscopy, without discontinuing blood thinning medications.

However, if your primary doctor has determined that your risk of blood clots is low and that you can safely discontinue blood thinning medications temporarily, please follow their instructions. In such cases, please refer to the separate Instructions on Medication Discontinuation regarding how many days you should stop taking the medication. Please have your primary doctor fill out the separate form for medication discontinuation, and bring the form on the procedure day.

Warfarin

Risk of blood clots associated with discontinuation of warfarin is variable, but if blood clots do occur, they can have serious consequences. Therefore, you **do not need to discontinue warfarin** prior to the colonoscopy. However, since it may be difficult to stop bleeding, we will perform **observation of the colon only**, and will not perform treatments and biopsies.

Anticoagulants (such as Eliquis, Lixiana, Pradaxa, and Xarelto)

We can perform biopsies without discontinuing the medication. However, we cannot perform treatment (polypectomy). In order to perform the procedure safely, **please take the medication after the colonoscopy is completed** on the procedure day.

Multiple blood thinners (excluding anticoagulants)

Including thienopyridines or ticagrelor

Risk of thrombosis from discontinuing medication is considered high, thus we cannot perform treatment (polypectomy) at our clinic. We will only perform observation, therefore you do not need to discontinue your medications.

Not including thienopyridines or ticagrelor

If you are taking up to one blood thinning medication (that is not an anticoagulant) at the time of the colonoscopy, you may undergo treatment (polypectomy). Please discuss with your primary doctor regarding whether or not you should temporarily stop taking your medications.

*If you are prescribed new medication after you make the colonoscopy appointment, please contact us to clarify if the medication may increase bleeding risk.

3) Intravenous sedation

If you undergo intravenous sedation, you may feel drowsy or lightheaded for a while, so you cannot drive a car or motorcycle or ride a bicycle until 6 am the morning after the procedure.

In addition, drowsiness may cause impaired judgment, so we recommend that somebody accompany you home as much as possible. Please do not make important decisions that require serious judgment on the day of the procedure.

There are several restrictions regarding the use of sedation, as below.

- ① **Only patients aged 18 to 75 years are eligible for sedation.**
- ② If you have myasthenia gravis, sedation cannot be used because it may worsen your symptoms.
- ③ Patients taking HIV protease inhibitors (ritonavir, saquinavir, etc.), HIV reverse transcriptase inhibitors (efavirenz, etc.) cannot undergo sedation.
- ④ If you are breast feeding, please refrain from breast feeding for 12 hours after the procedure, for your child's safety. We recommend you pump breast milk before the colonoscopy, if necessary.
- ⑤ If you have liver, kidney, or respiratory diseases, or if you are currently taking anti-epileptic medication, the doctor may decide that sedation is unsafe and discuss with you about cancelling sedation or adjusting its dosage.
- ⑥ If you use a wheelchair or cane, or if your gait is unstable due to injury or illness, please note that you are at increased risk of falling after using sedation.
- ⑦ **If you have glaucoma, suspected glaucoma, or have increased cupping of the optic disc, please consult an ophthalmologist before the procedure and confirm whether or not you can undergo sedation. Please obtain a medical document from your ophthalmologist stating you may undergo sedation, or obtain permission in person or by phone.**

* Glaucoma is a disease in which your eye (intraocular) pressure increases and your visual fields become narrow. In general, the fluid inside your eyeball increases, leading to increased eye pressure, which in turn increases pressure on the optic nerve. The sedative medication we use may increase eye pressure abruptly, which could cause headache, eye pain, eye redness, nausea, and in some cases blindness. Therefore, we may be unable to use sedation.

* Glaucoma is classified into acute closed angle glaucoma and open angle glaucoma. Sedation may be used for patients with open angle glaucoma and those with acute closed angle glaucoma who have undergone laser treatment.

* Increased cupping of the optic disc is a common finding seen in glaucoma. If you have this finding, please consult an ophthalmologist and confirm whether or not you have glaucoma. If you have already seen an ophthalmologist and have been told you do not have glaucoma, sedation can be used.

4 Precautions after the procedure

1) Abdominal bloating

You may feel some cramping or bloating because of the air introduced into the colon during the procedure. This should improve by passing gas.

To prevent dehydration, please drink plenty of water after the procedure.

2) Sedation

After using a sedative, drowsiness and lightheadedness will remain, so you will be asked to rest for about an hour in the clinic's recovery room. However, the effects of the sedative may still linger after discharge, so we recommend having an accompanying person to assist you in returning home whenever possible.

Additionally, please refrain from drinking alcohol, driving vehicles (cars, motorcycles, bicycles, etc.), engaging in physical activity, or using saunas until 6 a.m. the next morning.

3) Biopsy

If you undergo biopsy, please take only a light meal to prevent bleeding. Also, you may not drink any alcohol on the day of the procedure, as alcohol may increase risk of bleeding by stimulating the mucosa and increasing blood flow.

Rebleeding can occur after you leave the clinic. If you feel unwell, vomit blood, or notice black stool, please contact us immediately. If it is outside of our clinic hours, please go to the nearest emergency department.

4) Polypectomy

If you undergo polyp removal, there will be restrictions on diet, alcohol consumption, and activities such as exercise, travel, and bathing for up to one week, in order to prevent bleeding.

* If you feel unwell, have black stool or bloody stool, or experience severe abdominal pain or nausea, please follow the instructions which will be provided after the procedure.

5 Possible complications and risks

(Incidence rates are based on the 7th National Survey Report 2019–2021 by the Japan Gastroenterological Endoscopy Society.)

Our endoscopic instruments are cleaned, sterilized, and disinfected following the guidelines set by the Japan Gastroenterological Endoscopy Society. Individually disinfected instruments are used for each patient, so there is no risk of infection from the equipment.

1) Bowel preparation

The stimulation of laxatives may cause abdominal pain and ischemic colitis. And if there is an intestinal stricture (the intestine is narrowed due to the effects of cancer or inflammation), perforation (a hole in the large intestine) or intestinal rupture may occur due to increased intestinal pressure. If you experience severe abdominal pain, bloody stool, or vomiting, stop taking the laxative immediately and contact our clinic or visit a medical institution nearby.

2) Intravenous medication

These include allergies caused by anticholinergic drugs (drugs that suppress gastrointestinal movements), lowering blood pressure due to sedatives and respiratory depression. Its frequency is 0.072%, of which 0.002% are deaths.

3) Procedure and treatment

Incidents caused by endoscopy itself and biopsy include intestinal perforation and bleeding. Their occurrence rate is 0.046%, with no reported fatalities.

Procedural incidents from colorectal polyp treatment include bleeding and intestinal perforation. The treatments we perform at our clinic are mainly hot snare polypectomy (HSP), which is excised with a snare while applying thermocoagulation, cold snare polypectomy (CSP), which is excised with a snare without thermocoagulation, and endoscopic mucosal resection (EMR). The incidence rate of each was 0.484% for HSP, 1.539% for EMR, 0.237% for CSP and with a fatality rate of 0.024% for CSP and no fatalities have been reported for HSP and EMR.

※) If the bleeding is severe, endoscopic treatment or blood transfusion may be required. If it is difficult to stop the bleeding or if a perforation occurs, emergency surgery may be required, but we will respond appropriately and promptly.

4) Sedation

Procedural accidents of sedative use include respiratory depression, lowering blood pressure, shock due to allergies, drowsiness and lightheadedness, temporary amnesia symptoms (forgetfulness), inflammation at the injection site and falls. Rarely, nausea or vomiting may occur.

Sedatives may also cause a state of disinhibition, such as significant body movements. In such a situation, the risk of falling from the examination table or perforating increases, so safety is the highest priority, the examination may be discontinued at the discretion of the physician.

6 Other considerations

1) Patients aged 76 years and above

We do not perform colonoscopy in patients who are 76 years old and above. We will refer you to another hospital.

2) Patients under 18 years of age

We do not perform colonoscopy in patients who are under 18 years of age.

3) Pregnancy or possible pregnancy

Our clinic does not perform colonoscopy in women who are pregnant or may be pregnant.

We do not perform procedures when the risks of the procedure (including possible effects on the fetus) may outweigh the benefits.

4) Patients with brain aneurysm

If the size of your aneurysm is 4 mm or larger, please consult with your neurosurgeon and obtain permission for undergoing the endoscopy before the procedure. If you do not have permission from a neurosurgeon, you cannot undergo endoscopy at our clinic.

5) Patients with glaucoma, enlarged prostate, heart disease, arrhythmia, or hyperthyroidism

We may use medication that suppresses movement of the digestive tract (anticholinergic medication). Please notify us if you have any of the above conditions, as we may avoid use of the medication or use alternate medications.

*If we use anticholinergic medication, you must refrain from driving vehicles or riding motorcycles or bicycles until 6 am the following morning.

6) Patients on dialysis

Our clinic does not perform colonoscopy for patients receiving dialysis.

7) Those currently undergoing cancer treatment or currently suffering from cancer

If you are currently undergoing cancer treatment or currently suffering from cancer, please check with your doctor in advance about whether or not you can have an endoscopic examination and biopsy.

The final decision on whether or not to have an endoscopy will be made by our endoscopist. Therefore, please understand that we may refer you to your primary care physician or another medical institution.

8) Patients with neuromuscular disease (ALS, myopathy, myositis, myasthenia gravis, etc.)

Our clinic does not perform colonoscopy for patients with amyotrophic lateral sclerosis (ALS). For patients with other progressive or irreversible neuromuscular disease, please bring a medical note from your neurologist regarding whether you can undergo the colonoscopy and sedation. The final decision on whether to proceed with the colonoscopy and sedation will be made by the doctor performing the procedure. In addition, please bring an updated medical note each time you undergo a procedure, as your condition may have changed.

9) Patients who recently underwent surgery or endoscopic treatment

Our clinic does not perform colonoscopy for patients who have undergone abdominal surgery in the past 6 months, or for patients who have undergone endoscopic submucosal dissection (ESD) of the upper gastrointestinal tract in the past 2 months.

10) Weight limit

The endoscopy table's load limit is 130 kg (286lb.). For safety reasons, we cannot conduct the colonoscopy for patients who weigh over 130 kg on the procedure day.

11) Cancellation or rescheduling of the procedure

✕If the physician determines that the endoscopy cannot be safely performed, the test may be canceled or postponed.

Example: Significant hypertension (180/110 mmHg) or high intraocular pressure on the day of examination (intraocular pressure over 25) and symptoms such as eye ache.

*Please understand that there is always uncertainty in medical care and the test results are not completely guaranteed. We strive every day to obtain the best results and share any relevant information with you.

7 Alternative examinations

In addition to the abovementioned colonoscopy, examinations for the large intestine include barium enema, which uses a contrast medium such as barium and takes X-ray images of the colon, CT colonography (CTC), which is a 3D-CT scan of the colon, and colon capsule endoscopy. However, if any of these tests show abnormalities, biopsy cannot be performed during the examination.

8 Your right to withdraw consent

Even after submitting the consent form, you can withdraw your consent until the procedure begins. If you wish to cancel the procedure, please inform our staff.

Thank you for your understanding.