☐ Colonoscopy

(with endoscopic resection of tissue/polypectomy, if indicated)

Dear patient,

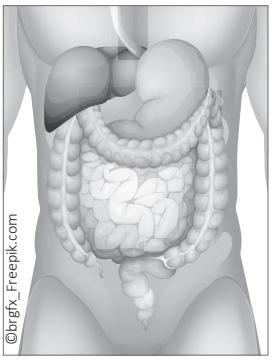
Endoscopy of the colon (lower digestive tract) is proposed for you. The purpose of this informed consent is to provide you with information and help to prepare for the patient-doctor discussion. Please read everything carefully before the discussion.

Why is colonoscopy recommended?

Endoscopy of the colon has been recommended for you either as a cancer screening technique (preventive colonoscopy) or to determine and possibly treat the cause of your symptoms. Although there are alternative imaging techniques, including X ray examinations with contrast, computed tomography or magnetic resonance imaging, your doctor is recommending endoscopy because it is considered the best diagnostic/treatment method to directly visualize the digestive tract and to take tissue samples and/or remove polyps at the same time.

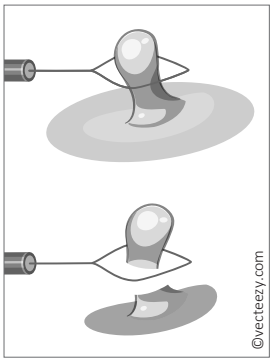
How is the endocopy performed?

During the procedure, you will normally receive a short-acting sedative (propofol) as the endoscopy itself can be unpleasant or even painful. A flexible optical instrument (the endoscope) is then inserted under direct visualization through the anus and advanced through the colon to the junction of the large and small intestine, in some cases into the adjoining small intestine (terminal ileum). By insufflating air into the digestive tract, the walls of the tract can be expanded which enables better visualization of pathological findings. During the procedure, tissue samples can also be taken. Removing tissue samples is usually not painful. The procedure usually lasts 10 to 30 minutes, in case of polypectomy (removal of polyps) sometimes longer. In rare cases (less than 5%), colonoscopy cannot be completed due to anatomical variations or changes (narrowing or kinking of the digestive tract) or an unclean bowel, despite the vast experience of the doctor. For these reasons, significant findings may even be overlooked in rare cases. In some cases it will therefore be necessary to repeat endoscopy or change to another method. In some cases, colonoscopy may need to be repeated if not all polyps that are present can be removed during the procedure, or if the findings of histological examination indicate that this is necessary.



How is the treatment/polypectomy performed?

Polyps are generally benign growths on the mucous membrane of the intestine. They should be removed and examined by a pathologist as early as possible as they may become malignant. Polyps (up to a certain size) can be removed with an electric loop. The stump is then cauterised to prevent bleeding. Sessile (flat) polyps may need to be raised by injecting medication into the surrounding mucous membrane, followed by removal of the polyp. Before colonoscopy, a blood count and coagulation screen (INR, PTT) are performed to assess your risk of bleeding. If you are taking anticoagulant medications (e.g. clopidogrel, ticagrelor, coumadin, apixaban, rivaroxaban, etc.) it will be decided if certain medications should be stopped prior to endoscopy. Medications should be taken or stopped only after consultation with the doctor. Aspirin (ASS) does not have to be stopped before endoscopy.



Necessary preparations

Before endoscopy, the colon must be cleansed thoroughly. For optimal bowel preparation, please follow the instructions with respect to intake of food, fluids and bowel cleansing. The cleansing solution will be handed to you along with detailed instructions on a separate sheet. Please avoid all foods containing grains and seeds (whole grain bread, tomatoes, kiwis, etc.) for at least three days before the procedure. Your doctor will inform you whether or not you should take your regular medication prior to the procedure.

Are there any risks or complications to be expected?

Despite the greatest care taken, complications may occur which can even become life-threatening under rare circumstances and necessitate further treatment or surgery.

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- In very rare cases, allergy or hypersensitivity to latex, sedatives, anaesthetic agents or other medications may cause respiratory disorders and/or cardiocirculatory failure, causing respiratory or cardiac arrest which necessitated immediate treatment and intensive care.
- Occasionally, the intestinal wall can be damaged by the endoscope, or when pumping in air, taking tissue samples or performing other treatment procedures. This can cause mild bleeding and/or pain. However, these symptoms usually do not require treatment and they resolved spontaneously.
- In rare cases (less than 0.1%), particularly after polypectomy, perforation of the intestine occurs, sometimes even days or weeks after endoscopy. This usually requires immediate treatment in a hospital and an operation with placement of a stoma if indicated. This complication can be associated with fever and/or pain, and if bacteria escape into the abdominal cavity, inflammation of the peritoneum (the membrane lining the abdominal cavity) can occur.
- In very rare cases, perforation of the intestine may result in blood poisoning (sepsis) or endocarditis (infection of the inner lining of the heart) necessitating further treatment and intensive medical care.
- Following polypectomy, your doctor will instruct you how to proceed in case of abdominal pain, bleeding or other symptoms.
- In rare cases, severe bleeding may occur secondary to therapeutic procedures, including polypectomy or removal of tissue for biopsy. Bleeding can usually be stopped via the endoscope by injection of medications or application of clips. Transfusion of blood or blood products may become necessary in rare cases only. The risk of transmission of HIV by transfusion of foreign donor blood has become extremely rare (less than 1 in a million).

Are there alternatives to endoscopy and polypectomy?

Pathological changes in the colon can sometimes also be visualised using alternative imaging procedures, including computed tomography, magnetic resonance imaging or capsule endoscopy. These examinations are considered less unpleasant as endoscopy. However, they are also considered sensitive when compared to colonoscopy. In addition, they do not enable direct evaluation of the colon and tissue or polyps cannot be removed. An open surgery, in which an incisision is made into the abdominal cavity, is the only genuine alternative to endoscopic treatment. This procedure is associated with higher risks for bleeding, injury to neighbouring organs, and a longer recovery phase.

Your doctor is recommending colonoscopy and endoscopic treatment, because, after evaluating all current findings, it is considered the examination method that is most appropriate for you.

Please note that you need to be picked up at the front desk after the procedure if you have received a sedation for colonoscopy. Moreover, you must not drive a car or any other vehicle for 12 hours after the procedure.

Important questions

In order for your doctor to identify any risks involved with the procedure as early as possible, we ask you to answer the following questions:

1. Do you have an increased tendency to bleed?
☐ No ☐ Yes

2. Are you currently taking anticoagulant medications (e.g. aspirin, coumadin, heparin, clopidogrel, rivaroxaban, apixaban)?
☐ No ☐ Yes

3. Are you regularly taking other medications?
☐ No ☐ Yes
If yes, please specify!

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4. Do you have a cardiovascular disorder (e.g. heart defect, heart valve defect, hypertension) or disease of the respiratory tract/lungs (e.g. asthma, chronic bronchitis)?
☐ No ☐ Yes
If yes, please specify!

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5. Do you have implants (e.g. cardiac pacemaker, defibrillator, joint endoprosthesis, artificial heart valve)?
☐ No ☐ Yes
If yes, please indicate!

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6. Do you have a family history of bowel disease?
☐ No ☐ Yes

7. Have you ever had an operation on the digestive tract or gynaecological operation before?
☐ No ☐ Yes

8. Do you have an allergy (e.g. hay fever or bronchial asthma) or hypersensitivity to certain substances?
☐ No ☐ Yes

9. Do you have a metabolic disease (e.g. diabetes, thyroid gland)?
☐ No ☐ Yes

10. Question for women of childbearing age: Could you possibly be pregnant?
☐ No ☐ Yes

Doctor's comments on the patient-doctor discussion:

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Patient's statement of consent

The recommended endoscopy, its nature and significance, risks and possible associated complications, possible alternatives as well as additional/subsequent treatments that may become necessary have been fully explained to me. I was given the opportunity to ask any questions that I considered important. A copy of this consent was handed to me after the patient-doctor discussion. I have no further questions and feel that the counselling was satisfactory. Therefore, after adequate time for consideration, I consent to the proposed examination. I also consent to any unforeseeable additional procedures that may become necessary for medical reasons. In consent to polypectomy (removal of polyps) during endoscopic examination.

☐ No ☐ Yes

I consent to being contacted for repeat colonoscopy, where indicated.

☐ No ☐ Yes

Wiesbaden, _____

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Signature Patient
or Supervisor/Authorized Representative

_____

Signature Doctor

Version: Juli 2022