

Please fill out with printed capital letters.

Name:

Mothers' name:

Date of birth:

SSN:

Information and consent form on virtual CT colonoscopy scanning

— Dear Patient,

Please read carefully all the information on the process of the examination, your tasks, and the possible adverse effects.

— General information

The CT (computer tomograph) virtual colonoscopy is a method suitable for the non-invasive examination of the lower section of the gastro-intestinal system, the colon. It uses CT equipment to make the internal surface of intestine, which is otherwise visible only with the conventional, more invasive (optical) colonoscopy (when an endoscope is introduced through the rectum). During CT colonoscopy we aim to find any polyps or other deviations possibly present in the colon. The polyps are growths projecting from the internal surface of the intestinal wall, from the part of which may develop a tumor. The primary objective of the CT colonoscopy is the early discovery of the polyps – in such state when they do not yet cause symptom, for example, bleeding – in order to remove them before the development of a tumor. With CT colonoscopy, not only the presence of polyps can be determined but also the other diseases of the colon (tumor, inflammation, diverticulosis).

CT (computer tomography) is an equipment using X-ray which, compounded with a complex computer, is capable of multi-plane two-dimensional imaging of the body. The 2-dimensional images generated this way is examined on the computer monitor. In CT colonoscopy, in addition to the 2-dimensional images, the computer, using the digital data obtained during the examination, generates spatial, 3 dimensional images of the colon. This allows the radiologist to examine the internal surface of the colon in full length, like the conventional colonoscopy.

If more accurate image is to be obtained on the function of an organ or the (possible) abnormalities within the organ, intravenous contrast agent is to be injected. The procedure involves radiation load and, if required, injection of intravenous contrast agent, however, you were sent to CT scan by your physician because from your point of view the information obtained this way is more important than the risk of radiation load and that of the injection of the intravenous contrast agent.

During pregnancy, the radiation exposure is to be avoided, the advantage of the application of X-ray examinations with or without contrast agent is to be carefully balanced against the possible risk. During pregnancy, injection of venous contrast agent is especially not recommended for CT scan unless the advantage resulting from its application exceeds the possible risks which is carefully assessed by the referrer and the radiologist conducting the examination. Beyond the avoidance of radiation, the iodine sensitivity of the fetal thyroid gland is to be considered when evaluating the possible risk/benefit assessment.

The contrast agents are secreted into the breast milk in small quantity and are absorbed from the intestines in minimal quantities. If the breastfeeding mother receives contrast agents containing iodine, the breastfeeding can be continued as per normal conditions.

— Examination procedure

On the day of the examination, we are expecting you at the specified time at the reception of our centre. Our colleague will show you to your changing room where you can change. The examining assistant will ask several questions on your complaints, symptoms, former examinations, possible earlier diseases, surgeries, treatments. Please bring your reports, final reports and - if you have received any - records, CD documentations of the examinations and hand them over to provide more information for the assessment of the examination. At this time, if you require, you can ask any remaining questions to our colleague.

Prior to the beginning of the examination please visit the toilet one more time. After this you will be led to the examination room and ask to make yourself comfortable - usually lying on your back - on the examining table. We inject a thin branula into your arm to be able to inject the injection for the proper laxation of the bowels and the venous contrast agent outlining the blood vessels.

The stoppage of bowel movements is done with smooth muscle antispasmodic injection. The effect of the drug lasts for 10-15 minutes, will not cause sleepiness but may have side effects which are negligible compared to its advantages: mouth dryness, quick heartbeat, urine retention which are usually mild. In rare cases, allergic reaction may occur (rashes, circulatory and respiratory symptoms, in severe cases life-threatening state, shock).

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Your eye muscles may relax which cause eyesight impairment, so in case of vision symptoms, please do not drive until it is over! If you feel such symptom or pain is felt in your eyes, immediately consult an ophthalmologist because a latent disease may exist in the background!

After this, the colon is to be filled with air for the proper quality examination. For this - while you are lying on your left side - a skilled member of the examination staff leads a thin, flexible, short plastic pipe into the rectum, and we carefully begin the inflation of the bowels with air which is done with manual pumping. During this you may feel some transitional tension in your stomach which is only rarely painful and will go away in a few minutes. The full inflation lasts only a couple of minutes and is followed by an informational series at a low radiation dose to ensure whether the bowels are adequately filled with air. After the informational series the examination will begin. During the movement of the examination table the data collection of the examination takes place, our colleague will ask you to inhale and hold the air - this is required only for a short time, 20 to 30 seconds.

After finishing the first examination series we will ask you to turn back to your back - in certain cases to side - then iodine contrast agent will be injected to the vein through the branula using a contrast agent pump, then we perform the second series while inhaling. (If part of the inflated air is discharged from the colon, it will be replenished before the commencement of the second scan series.) When injecting the contrast agent, you may experience a body-wide sensation of warmth, a bitter, medicine-like taste in the throat and a warm sensation similar to urinating in the bladder area. All this is normal and goes away in a short time.

The second examination series makes the examination complete. The computer sends the measured data to a workstation suitable for assessment and to a suitable data storage area. We remove the air inflation tube and the branula from your arm. You may dress, visit the restroom, then - while under our supervision - you can have a rest from the stress of the examination in 15 - 20 minutes. After this you may leave and resume your normal daily routine (as it was mentioned earlier, the inflation of the air may cause sensation of swelling, fullness which can be reduced with anti-flatulent medicine). The duration of the examination is typically 15-20 minutes. During the preparation of examination series, you stay alone in the examination room but our colleague can see and hear you and you can talk to each other.

— Benefits of examination

The CT virtual colonoscopy is a minimally invasive method which, in case of adequate cleaning, yields an image with diagnostic value equivalent to the conventional colonoscopy on the internal surface of the intestine. In addition to this, it even "sees" which cannot be seen during the conventional colonoscopy: the colon wall in its entire cross section and the entire abdominal cavity, thus it provides additional information on all abdominal organs. During CT colonoscopy, the risk of intestinal perforation (hole in the intestinal wall) is much lower than during the conventional colonoscopy. In case of incomplete (unfinished) conventional colonoscopy, that is if the instrumental investigation of the entire length of the colon cannot be done - about 10% of the cases - the CT colonoscopy is usually realizable. The CT colonoscopy is tolerable better, it does not require the application of painkiller or sedative.

— Possible hazards, adverse effect and their avoidance and prevention

X-ray is used during the examination. During a series of CT colonoscopy examination, the level of radiation load is 5 mSv which is equivalent to a radiation dose one receives in about 2 years from the background radiation. The examination usually consists of two series, the first after the air inflation of the colon and the second after the injection of the intravenous contrast agent.

If intravenous contrast agent is used for the examination, it is possible to have an informational assessment of the other internal organs but in such cases the administration of the contrast agent may also cause undesirable side effects. The contrast material given in the second phase is an iodine-containing compound that is suitable for imaging blood vessels and examining the vascular supply of organs and tissues.

For the administration of iodinated contrast agent required during the CT scanning, the following must be considered in case of patients taking medication for diabetes in case of certain products:

Patients with diabetes taking METFORMIN:

1. **NO CHANGE NEEDED** in the administration of METFORMIN, if
 - they have no acute renal insufficiency,
 - their eGFR value > 30 ml/min /1.73 m²

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2. THE TAKING OF METFORMIN-BASED MEDICINE **MUST BE SUSPENDED FOR 48 HOURS FOLLOWING THE ADMINISTRATION OF THE CONTRAST AGENT**, then it may be resumed afterwards only if the control eGFR value has not changed significantly in case of patients who

- have no acute renal insufficiency and the eGFR value $< 30 \text{ ml/min / } 1.73 \text{ m}^2$

Please check if you are taking diabetes medicinal product containing metformin, if yes, then consult with your physician on the method of its administration! With normal kidney function, the contrast agent will not damage the kidney, but it is **IMPORTANT** to consume ample amount of liquid (min. 1.5-2 litres!) in the days before and after the contrast agent CT scanning.

In case of contrast agent CT scans the contrast agent is usually introduced into the body through the cephalic vein, usually using a pump (injector). You may feel warmth, hot sensation for a short time during injection. Metallic taste, possibly nausea, rarely vomiting may occur. In case of those prone to it, the contrast agent may exit from the blood vessels, causing a stretching, stinging sensation. Should such sensation occur, please notify us! This does not cause any damage, absorbs without trace. The bandaging of the limb is recommended.

The contrast agent is a chemical compound containing iodine which is suitable for outlining the blood vessels and the examination of the circulation of organs and tissues. The contrast agent, as any other medicine, may trigger hypersensitivity. The hypersensitivity may occur not only due to the iodine itself but to the complex of the iodine and the molecule attached to it, that is, the compound. Contrast agent hypersensitivity (allergy) occurs rarely. Symptoms: swelling of face, lips, tongue, throat, coughing, itching, nose running, sneezing, urticaria, dyspnea, sensation of suffocation. Should these or other symptoms occur after the administration of the contrast agent, immediately notify the examining operator. Be advised that these symptoms may occur later, within 24 hours, in such case please report to your attending physician or at the emergency ward! In most cases the allergy is mild, severe allergy is rare. It is extremely rare to have anaphylactic (hypersensitivity) shock state which, in extreme cases, may lead to circulatory collapse and cardiac arrest. Our institute is equipped and prepared to prevent a possible allergic reaction; the necessary clinical background is available.

During the examination we use a medicine which relaxes the wall of the colon, however, this medicine cannot be used in case of glaucoma. It is important to call the attention of the examiners if you have glaucoma.

In a very small part of cases the air inflated to the colon during the examination may cause the damage, perforation – penetration – of the intestinal wall. This may occur less than once out of 2000 cases.

If you notice new bleeding from the rectum in the days before the examination (in this case we mean not the inconvenience caused by the bowel cleaning before the examination but for example bleeding from haemorrhoids), inform the staff on it because air embolism may develop from the bleeding area due to the air inflation so the examination cannot be performed! If colonoscopy was performed within a week prior to the examination, and small polyp was chipped off or sample was taken from the intestinal wall, the CT colonoscopy cannot be performed due to the increased risk of the intestinal wall damage.

— Limitations of the examination

If the bowel cleaning is inadequate, the faecal matter remaining in the intestines will render the examination unassessable. Therefore it is important to do the bowel cleaning as described above. Regarding that the quantity of the remaining faecal matter and so the assessability of the images will be visible only when the examination is complete, the records being reconstructed and overseen, in case of payable examination we cannot reimburse the price of the examination due to the inadequate cleaning!

Overweight - over 150 kg - patient or one with large circumference, due to the load-bearing capacity and the dimensions of the CT examination equipment, cannot be examined.

The CT colonoscopy is strictly a diagnostic method. If during the examination a significant size (larger than 6 mm) polyp is found, its removal requires the performance of a conventional instrumental colonoscopy. Of course, it is not needed to view the entire colon with the optical endoscope, we only need to get to the already known polyp which means less load.

Should you have any further questions, ask the medical personnel performing the examination or the specialist controlling the examination!

As for any diagnostic examination, the virtual CT colonoscopy and the contrast agent CT scanning also require that you give your consent if you request to have them performed according to the law on health. Without your signature on the informed consent the examination cannot be performed.

— **Thank you for your cooperation, we wish you good health.**

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Examination questionnaire

Please answer the questions below, marking your answer with an X using the check box.

Are you pregnant?

☐ Yes/ It is possible ☐ No

Please note that if the answer is Yes/It is possible, you have to fill out the relevant pregnancy questionnaire & consent form before undergoing an examination that involves radiation.

Are you aware of having/ do you have hypersensitivity to any kind of medicine?

☐ Yes ☐ No

Have you ever been administered contrast medium during a CT, angiography (DSA) or X-ray examination?

☐ Yes ☐ No

If yes, did you have any kind of allergic symptoms?

☐ Yes ☐ No

Do you have asthma?

☐ Yes ☐ No

Do you have hypertension (high blood pressure)?

☐ Yes ☐ No

Do you have diabetes?

☐ Yes ☐ No

Do you have gout?

☐ Yes ☐ No

Do you have any kind of untreated thyroid disease?

☐ Yes ☐ No

Do you have any kind of kidney disease (previous kidney surgery, proteinuria)?

☐ Yes ☐ No

Do you have a contagious disease (tuberculosis, hepatitis, etc.)?

☐ Yes ☐ No

Do you have glaucoma?

☐ Yes ☐ No

Are you currently breastfeeding?

☐ Yes ☐ No

Do you have any other significant diseases?

☐ Yes ☐ No

Other significant disease

Height (cm)

Body weight (kg)

Consent form

I, the undersigned, hereby declare that I have been fully informed both in written and verbal form, especially about the nature, purpose and steps of the procedure in a way that I can understand. I have also been informed about the possible complications, benefits and risks of a missed examination, and my rights about consenting to the examinations and interventions.

I was given the opportunity to ask further questions, my questions about the procedure (if I had any) were answered to my satisfaction, and I understand what was said. I was given the opportunity to learn the name, qualification and position of the personnel directly involved in the procedure. I have no further questions and I do not need further time to think. I have been given sufficient time to make my decision and I give my consent under no duress and of sound mind.

I understand the nature of the examination and agree to the virtual CT colonoscopy scanning.

Signature of the patient (or legal representative)

I have been informed that for evaluable results sometimes it may be necessary to administer contrast medium. I acknowledge that if I reject the administration of the contrast medium, the images might be less informative, and this may result in adverse consequences, for which Affidea is not liable.

☐ I agree to the administration of intravenous contrast medium if necessary.

☐ No, I do not agree to the administration of intravenous contrast medium.

Signature of the patient (or legal representative)

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Name:

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If the PATIENT CANNOT MAKE A STATEMENT and/or sign on their own behalf, the reason for this

- ☐ Minor (under the age of 18)
☐ Vulnerable adult (diminished capacity/incapacitated)
☐ Other – please specify

Full name of legal representative
(Please completed with printed letters.)

Date of signing the statement