

Pozitron Diagnosztika Kft.		Dokumentum típusa:melléklet (me)
TAJÉKOZTATÓ Cardio/CT vizsgálathoz angol nyelvű		Dokumentum száma:me-02-M-11-001 Hatályba lép: 2014.09.30.

Informed Consent Form for Cardio-CT examination

Dear Madame/Sir, Dear Patient,

You have presented yourself to our Institute for a Cardio-CT examination. Of course, you have to give a written consent for the examination. To be able to bring the decision easier, we inform you in advance about the process of the planned examination, about its possible risks and consequences. This information sheet contains the most important information about the examination, according to that you can prepare to the prior consultation with the doctor.

Please bring your previous findings to the examination!

Process of Cardio-CT examination:

CT, that is computer tomography, is a special X-ray examination that makes possible to analyze the body in layers and to represent different parts of the body with cross-section images. With the help of CT examination the condition of heart coronaries, the sites, the sizes and the compositions of coronary narrowings caused by atherosclerosis can be accurately defined.

During the examination you will lie on the examination table that will continuously slip in the ring of the CT equipment. The opening is wide, so in most of the people it does not cause claustrophoby. Through the microphone built into the equipment you can talk with the assistants at any time.

During the examination you have to lie immovably and relaxed, and you have to **breathe according to the instructions** of the doctor.

To obtain appropriate image about the coronaries contrast medium with iodine will be injected into one of your veins, most often into the vein of the elbow, through a canula implanted previously. During the injecting of the contrast medium a slight, harmless warmth feeling may develop, that disappears after a few seconds.

Cardio-CT examination is totally painless and usually lasts for 3-5 minutes. A few further hours are needed to process, evaluate computer images and to prepare the finding.

With the conventional procedure heart coronaries can be represented only by invasive methods – which involves penetration into the body -, the so called cardiac catheterization examination, during that X-ray contrast medium is injected directly into the coronaries via the catheter led up by the artery of the thigh or the arm. This method can be replaced by the cardiac computer tomography. In case of claim your attending physician also gives information willingly about other possibilities and gives explanation why he/she recommends the coronary-CT in your case.

Possible side effects:

None medical examination can be totally free from risk!

CT is generally a routine procedure of low risk. The injected contrast medium with iodine very rarely causes side effects. Complications, which may develop during and shortly after the examination, can be the followings:

- **In extremely rare cases** to the effect of the injection beside the damage of the vein wall the skin, the surrounding soft tissue structures or nerves may also be damaged (e.g. abscess at the site of the injection, tissue necrosis, irritation of the nerves and veins) that may require medical or surgical intervention and may cause irreversible alteration or complaint (scars, numbness).
- **Very rarely** moderate allergic reactions (hypersensitivity reactions) may develop against the contrast medium, the signs of which can be nausea, itching or skin rash. Most commonly these disappear spontaneously, they do not require treatment.
- **In very rare cases** allergic reactions accompanied by the swelling of the mucous membranes of the throat, breathing and circulation disorders may develop, which require immediate intensive medical treatment. In case of the existence of certain conditions, these symptoms may cause life-danger. In case of allergic reaction the doctor performing the examination prevents the worsening of the condition with appropriate medical treatment and reverses the allergic reaction.
- **In very rare cases** in kidney or thyroid gland disorders, which already exist at time of the injection, the contrast medium may further worsen the kidney functions or may cause the hyperfunction of the thyroid gland. In this case infusion or other medical treatment is necessary.

You are exposed to X-ray radiation during the CT examination. The applied X-ray radiation dose is low, so you do not have to be afraid of immediate harmful damage. During the coronary-CT examination the applied X-ray radiation dose corresponds to cc. ½-2-year background radiation arriving from the environment. This radiation dose, theoretically, primarily in case of persons under the age of 35, may increase the risk of subsequently developing tumourous diseases in a minimal grade (cc. with 0.05%), so this risk increase from the natural risk of cc. 30% to cc. 30.05%.

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During pregnancy X-ray radiation can be dangerous to the child to be born. That is why it is definitely important to inform your doctor about the fact of pregnancy or even about its suspicion!

The cardio-CT examination is performed by ECG control.

Before the examination in some people it can be necessary to give beta-blockers, short-lasting medicines that slow down heart function. If you are allergic to any drugs or you suffer from a disease in which giving beta-blocker is not recommended (severe asthma) please inform your doctor!

Before the examination in some cases nitroglycerine aerosol, a vessel dilator is sprayed under the tongue, which helps the accurate diagnostics by dilating the coronaries. In connection with this rarely, transiently low blood pressure, dizziness and dull headache may occur. The drug is eliminated from the body about 10-15 minutes, so the discomfort caused by it ceases.

What to pay attention to?

Before the examination:

Please follow accurately the instructions of the doctor (e.g. in connection with meal/fluid consumption, taking drugs). Attention of diabetic persons is called to that drugs against diabetes containing metformin can interact with the contrast medium and can cause disturbance in the function of some organs (e.g. in patients with pre-existing poor kidney function, it can even cause kidney failure). For protection of your kidney function if you are taking medicine containing metformin, you have to omit it 48 hours before and after your examination. Ask your doctor if you have to stop taking your drugs, and if yes, for how long time. If your doctor did not decided differently, do not eat at least 4 hours before the examination, but drink abundantly, and at least 1 hour before it do not smoke! On the day of the examination do not consume coffee, tea, cola or other drink that has a stimulating effect.

After the examination:

If your doctor did not decided differently, drink a lot after the examination to help the reconstruction of the fluid homeostasis of the body and the fast excretion of the contrast medium.

If on the day or on the next day of the examination itching, sneezing, pain, nausea, loose stool or other symptoms may occur, inform your doctor immediately!

We call your attention that at the area of the centre only one companion can stay with the person waiting for the examination!

If you have any further questions please call our colleague on the following numbers:

Positron-Diagnostics Center

e-mail: info@pet.hu; Address: 1117 Budapest, Hunyadi J. út 9., Hungary

Fax: +36-1-505-8889, Tel: +36-1-505-8888, +36-1-505-8881,

I have read and accepted the aboves.

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Date

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Signature