

CORONARY ARTERY CT-ANGIOGRAPHY WITH ^{18}F -Na PET-SCAN INFORMATION SHEET

You were prescribed a coronary CT (computed tomography) angiography in order to visualize your coronary arteries (that vascularize your heart). We propose you to complete this exam by adding a PET-scan (positron emission tomography) with ^{18}F -Na staining, that would be performed in the same time.

Coronary artery disease results from cholesterol deposits inside the internal wall of the arteries of the heart (coronary arteries). These cholesterol deposits accumulate within a plaque, the atheromatous plaque. Its constitution, growth and evolution involves complex and often intricate mechanisms, in which inflammation of the plaque plays an important role. We know all the risk factors that aggravate the genesis and evolution of atheromatous plaques: tobacco, excess lipids in the blood, high blood pressure, diabetes, physical inactivity, overweight... Nevertheless, there is an important individual variability which accounts for our natural predisposition to "promote" plaques and which depends on our genetic background. This individual "intrinsic risk", which is unique to each of us, explains that more than half of coronary heart disease occurs in patients who have little or no cardiovascular risk factors. This "intrinsic risk" is then further amplified with accumulation and combination of risk factors.

When the plaque enlarges enough to partially obstruct the coronary artery, the blood flow in that artery gradually decreases and the heart muscle is no longer oxygenated enough. This is called angina pectoris (or angina), sometimes manifested by a very characteristic pain, which can be treated with medication and / or by revascularizing the narrowed artery: angioplasty or bypass surgery. As is often the case in medicine, pain has the value of an "alarm signal" leading the patient to consult and then allowing diagnosis and treatment.

However, atherosclerotic plaques are subject to another evolutive risk. Under the effect of inflammation, they can turn into a structural transformation cycle (referred to as "unstable plaques"), resulting in a more or less partial rupture of the plaque. By exposing its contents to the circulating blood, the plaque will trigger a coagulation phenomenon leading to a blood clot: the thrombosis. This thrombosis will most of the time be responsible for myocardial infarction, which results from the death of a greater or lesser amount of cardiac fibers which are no longer vascularized at all, the clot brutally and completely occluding the artery. This risk is not inevitable and most of the plaques, even inflammatory, stabilize and heal (particularly by calcifying themselves) and are never talked about. Unfortunately, among those that develop unfavorably, a large number plaque rupture occurs before the plaque is large enough to partially obstruct the artery and therefore before the patient suffers from angina. Instead of a slow progressive phenomenon (the growth of plaque) accompanied by an alarm signal (pain), we are therefore witnessing, on the contrary, a brutal phenomenon (thrombosis leading to myocardial infarction), without warning signs and therefore clinically unpredictable. It is to avoid this brutal and severe

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phenomenon that cardiologists vigorously track down and treat the risk factors that we mentioned above. However, two important elements escape them: the natural predisposition to make plaques (even if we often find family contexts), and the evolutivity of the plaque towards the risk of rupture.

The test that we propose you today aims at clarifying these two elements. Of course, it is proposed to you after a pre-selection based on clinical assessment, biological and imaging tests (such as ultrasound of the arteries and / or the heart, myocardial perfusion imaging and / or coronary artery calcium score) which identify you as at higher risk than the average population. This examination consists of two parts carried out simultaneously:

- The coronary CT angiogram with intravenous injection of iodine contrast agent, which has already been prescribed to you, and that allows to diagnose and evaluate the degree of your coronary arteries: this examination makes it possible to analyse the number and location of the coronary atheromatous plaques, their more or less obstructive nature, and their morphological characteristics in search of signs of "unstability";
- The ^{18}F -Na PET scan: this test will reveal phenomena of micro-calcifications inside the plaques, that make them more prone to progress towards rupture.

The following information forms will provide you more details about the coronary CT angiogram that was prescribed to you, and the ^{18}F -Na PET scan, knowing that they will be carried out simultaneously, during the same acquisition and on the same machine.

Coronary artery CT angiography

CT-scan makes it possible to provide sectional images of the human body by means of X-rays. In your case, it will allow, after injection of iodine contrast agent, to visualize your coronary arteries.

This injection of a contrast agent requires that you carefully complete a pre-CT-scan questionnaire. If a question is not clear to you, don't hesitate to ask for assistance. In general, do not hesitate to provide any information that you feel important to communicate and to inform us of any serious diseases, allergy, etc...

- The CT-scan technique is based on X-rays. The doses used are low and precautions are taken to limit the exposure of the area examined to the strict minimum. Doses range from 5 to 10 mSv. As a comparison, the annual natural irradiation of the inhabitants of certain granitic regions in France (Corsica, Brittany, etc.) is around 2.5 mSv. However, caution is mandatory for pregnant women who should not undergo this examination. For women, it is important to report if you may be pregnant, or if you did not have effective contraception during your last sexual relation.
- You will need to be fasting, i.e. not having eaten for at least 2 hours. It is desirable to be well hydrated, by drinking at least half a liter of water before the exam and by frequently

drinking water the rest of the day (at least 1.5 liters). Ideally, because of the contrast product used for the CT-scan, sparkling Vichy water is the most suitable. If you are on medication: you can take it. As a systematic allergy prevention, you will have to take 1 tablet of Aeries (Desloratadine) the evening before, and the morning of the examination.

What is the course of the test?

You will be greeted by an imaging technician who will inform you about the progress of the examination and ask you questions about your current treatments, the reason for your visit and your medical history. Do not hesitate to ask him/her any questions that seem important to you. You will be comfortably installed on an examination bed that will move several times in the opening of a ring (and not of a tunnel). With the exception of certain tests which require special positioning, you will be lying on your back, arms above your head.

The duration of the test can vary depending on the region examined (between 5 and 20 min). It is important to stay still, sometimes stopping breathing for a few seconds on demand. During the entire test, you are never alone: behind the glass, the healthcare team can see and hear you perfectly. The injection of iodine contrast agent will be useful to improve the visibility of the vessels and tissues. It is done by a small catheter placed in a vein, most often at the bend of the elbow. You may then feel a heat which will disappear quickly. The product is eliminated by the kidneys in a few hours. If too fast, you may be given a beta blocker to temporarily lower your heart rate.

Once the test is finished, your pictures will be given to you and you can leave as normal. The report of your examination will be sent to your home or to your doctor.

Don't forget to take :

1 tablet of Aeries (Desloratadine) the night before the test, and 1 tablet in the morning of the test.

Don't forget to advise us:

- If you have kidney problems, allergies (asthma, eczema, hives ...) or if you have undergone any particular reaction during another examination with the injection of an iodinated contrast agent.
- If you are taking regular treatment for diabetes.
- If you are (or can be) pregnant.
- If you are breast-feeding.

Don't forget to bring:

- All previous examinations (blood tests, previous CT-scans, other imaging ...) likely to contribute to the realization of the test and facilitate the diagnosis.
- Recent renal blood test with serum creatinine of less than one month unless it has been carried out at Princess Grace Hospital.

After the test:

- After the test, monitoring may be necessary due to the injection of contrast agent. To accelerate the elimination of the product, drink plenty of water (except special diet or kidney dialysis).

What are the risks of injecting contrast agent:

Contrast injection is a very common procedure, usually very well tolerated. However, as with any medication, some adverse reactions can occur:

- Venous puncture can cause a small, minor hematoma, which will resolve by itself within a few days.
- During the injection, under the effect of pressure, the product may leak out of the vein under the skin. This complication is rare (one case among hundreds of injections, generally without serious consequences), and may exceptionally require a local treatment.
- Iodine injection may cause an intolerance reaction. These unpredictable reactions are more common in patients who have had a poorly tolerated injection of one of these products or who have a history of allergic reactions. They are generally transient and not serious. They can be more severe, resulting in cardio-respiratory disorders and require treatment. Serious complications (death) are extremely rare. To prevent this risk of intolerance or allergy, a systematic prescription of antihistaminic (anti-allergic agent desloratadine) will have been given to you when making the appointment: 1 tablet to be taken the night before, and 1 tablet in the morning of the test.
- Kidney accidents, also linked to the iodine product, are also possible, especially in certain patients suffering from diseases that weaken the kidney (chronic renal failure, diabetes with kidney damage, etc.). Special cautions will be taken in the eventuality of particular risk factors, which will be identified during the dialogue between the team and you, prior to undergo the test.

¹⁸F-Na PET-scan

You are going to perform a ¹⁸F-Na PET-scan. This product (referred to as radiotracer) is not allergenic. This very weakly radioactive tracer (18 µSv per MBq of tracer injected) is injected into a single vein in the forearm. ¹⁸F-Na fixes mainly to the bones, but also to the tissues where calcifications or micro-calcifications are located. These are precisely the micro-calcifications that exist in the atheromatous plaques (cholesterol deposits) located in the arteries that we want to visualize, and more particularly those located in the arteries of the heart (coronary arteries). Indeed, these atheroma plaques containing micro-calcifications are more likely than others to partially rupture, with the resulting risk of myocardial infarction, even if these plaques are not obstructive enough to cause painful symptoms (i.e. event in the absence of angina).

¹⁸F-Na PET-scan will be performed at the same time as a CT-scan of the coronary arteries (see above the information form on the coronary artery CT angiography).

¹⁸F-Na PET-scan is a rapid examination: ten minutes under the PET camera. You will breathe normally (but slowly) during the exam.

- You must be fasting for 2 hours except for the water necessary for your hydration.
 - Under no circumstances should you be accompanied by, or be in contact with, a pregnant woman or a young child all day long.
- For women, it is important to report if you may be pregnant, or if you did not have effective contraception during your last sexual relation.

WARNING:

- If, for technical reasons, the delivery of the product to our hospital had to be canceled, or the delivered lot invalidated for use on a patient, your examination would be postponed as soon as possible. **It is possible (but fortunately exceptional) that the exam is canceled at the last moment.** We are in no way responsible for this fact, the supplier laboratory being likely to prohibit the use of the lot at the last moment for your safety.
- **¹⁸F-Na is not an experimental tracer. This tracer obtained the health authority's agreement for bone indications or other diseases, which guarantees the safety of its production and the long term experience we have with it. However, it is not yet "approved" for the coronary indication that we propose you by some foreign private insurance company, although several scientific publications provide evidence for its effectiveness.**

I, undersigned (Name, First name):

Certify having read the information form entitled: **Coronary artery CT-angiography with ¹⁸F-Na-PET-scan**, comprising 5 pages (including this one), having understood it, or at least having being explained it and having observed the instructions included in it.

I agree that the anonymised imaging data may be used for medical research purposes (*cross out this statement if you object*).

Monaco, (date and signature):

CHECKLIST :

- 1/ Take 1 tablet of Aerius (desloratadine) the night before the test, and 1 tablet in the morning of the test,**
- 2/ Bring your creatinin blood test,**
- 3/ Drink plenty of water before and after the test (Vichy water recommended),**
- 4/ No other food or substance than water 2 hours before the test.**