

UOC RADIOLOGY - UOC NEURORADIOLOGY

INFORMATION LEAFLET, EXPRESSION AND ACQUISITION OF INFORMED CONSENT FOR THE PATIENT TO PERFORM CT WITH CONTRAST MEDIUM

Dear Patient,

The procedure we recommend you to do requires your consent so that, through this information sheet and a conversation with the doctor, you can make an informed decision. You will receive detailed information about possible complications associated with the diagnostic procedure recommended. We kindly ask that you carefully review the following details before the procedure and address any questions, doubts, or requests for clarification with us, so you can make a well-informed, responsible, and calm decision.

WHAT IT IS

Computed Tomography (CT) is a diagnostic imaging technique that uses ionizing radiation beams (X-rays). These beams pass through the body, producing sectional images (tomography) of internal structures with the help of a computer (computed). Modern CT devices capture entire volumes of the examined body area (acquisition phase) and subsequently reconstruct the images in multiple spatial planes (post-processing phase).

CT scan can be used to examine any body part (e.g., skull, neck, chest, abdomen, limbs), providing detailed and simultaneous views of bones, soft tissues, organs, and blood vessels. Certain CT scans require the use of a contrast agent to diagnose various conditions. Compared to traditional X-ray imaging, CT scan provides superior anatomical detail but exposes the patient to a higher dose of ionizing radiations. Its use should be avoided unless there is a specific clinical indication. Childbearing years women must exclude the suspect of pregnancy due to potential risks to the fetus. In some cases, artificial intelligence systems may process the images, comparing them with a database of anonymized clinical cases. The AI-generated report, is attached to the images and the result is then analysed by the radiologist. Data processing complies with privacy laws.

PURPOSE

CT scan is an advanced diagnostic procedure used to investigate traumatic, oncological, inflammatory, and emergency conditions in any body area based on clinical indications.

HOW THE CONTRAST-ENHANCED EXAM IS PERFORMED

Upon arrival, you will be welcomed by our staff and guided to the dedicated room. You will lie on the CT scan table, where a nurse or doctor will insert a cannula needle, typically in the arm (at the elbow fold or hand). Through this, an iodine-based contrast agent will be administered via infusion or an automatic injector. The quantity of contrast agent used depends on the procedure, the diagnostic examination, the body region and your weight. The procedure generally lasts 15-30 minutes. No recommendations against daily routine activity resume are expected.

Patients are advised to be fasted for six hours before the exam for patients who have to take premedication for allergies or heart and abdominal scans. For other body regions, fasting is not required. Adequate hydration (at least 1.5 litres of water) is recommended the day before and the day of the exam. During the scan, you will lie on a table that moves inside a circular device (gantry) where the X-ray source and detectors are situated. Collected data are processed by a computer, in order to

create detailed images of the examined area. It is possible to generate 3D anatomical reconstructions or use AI software for complex data analysis.

WHAT THE CONTRAST AGENT IS AND ITS PURPOSE

The contrast agent is a liquid medication containing iodine, injected intravenously. It enhances the density differentiation of anatomical structures, allowing the visualization of arteries, veins, lymph nodes, and possible lesions in the organs examined.

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EFFECTS OF IONIZING RADIATION

The dose of ionizing radiation in a CT scan varies according to the type of exam and the anatomical body region. The biological risk from X-ray exposure is stochastic, meaning probabilistic (similar to smoking exposure). The risk is statistically rare and unpredictable, though its probability increases with higher doses. However, the severity of potential damage does not correlate with dose levels but rather with the occurrence likelihood.

POSSIBLE EARLY OR LATE COMPLICATIONS

Shortly after contrast agent administration, some patients may experience a sensation of warmth (sometimes intense) spreading from the arm to the throat, head, abdomen, and legs. This sensation is not a cause of concern and it typically subsides within 30-40 seconds.

In rare cases (for physiological reasons, veins weakness etc), the vein where the cannula was placed may rupture, causing contrast agent leakage into the injection site. This may provoke a swelling that will be treated with ice and topical ointments medications, even at home if necessary.

Potential allergic reactions to the contrast agent may be immediate or delayed. Based on severity, these reactions include: Mild: nausea, vomiting, skin rashes, pain at the injection site. Moderate: shortness of breath, low blood pressure, rapid heartbeat. Severe (life-threatening): severe arrhythmias, bronchospasm, cardiac arrest, acute kidney failure. For these rare cases, our facility is equipped with appropriate staff, medications, and equipment to manage such emergencies. Delayed reactions (from one hour up to seven days after injection) may include skin rashes, flu-like symptoms or gastrointestinal disorders. In such cases, consult your primary care physician.

CONTRAINDICATIONS

Pregnancy is the only absolute contraindication for a CT scan. If you are pregnant or if you suspect to be pregnant, inform the radiologist. In our Facility, CT scans are conducted only after assessing their appropriateness based on scientific research and guidelines.

RADIOLOGIC RISK OF CONTRAST-ENHANCED CT SCANS

Radiation doses in CT scans can be classified from Class II to IV:

Class II: $1\text{mSv} < \text{effective dose} < 5\text{mSv}$

Class III: $5\text{mSv} < \text{effective dose} < 10\text{mSv}$

Class IV: $\text{effective dose} > 10\text{mSv}$

In this context, the risk-benefit balance is highly favourable.

In consideration of the information contained into this form and discussed with the physician who recommended the procedure, patients may request further clarifications to the radiologist.

GENERAL RECOMMENDATIONS FOR SCHEDULED EXAMS (NOT URGENT)

- Fasting for six hours if undergoing premedication for allergies or heart/abdominal scans; fasting is unnecessary for other body regions.
- Continue regular medication (unless otherwise indicated) and maintain hydration (it is important to be well hydrated).
- Bring previous medical records, including radiologic images.
- Some blood test values may be altered for 24 hours post-scan.

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CT SCAN WITH CONTRAST AGENT
 Information and Consent Form

Last Name _____ First Name _____

Place of Birth _____ Date of Birth _____

Address _____ Street _____

Prescribing Physician _____ Primary Care Physician _____

RISK ASSESSMENT QUESTIONNAIRE FOR CONTRAST AGENT

Requested Examination (as specified into the referral) _____

The information collected in this questionnaire is essential for assessing accurately the risks associated with contrast agents. If in doubt, consult your primary care physician.

Creatinine (from a blood test within the last 3 months) eGFR Value (Glomerular Filtration Rate, available in lab reports): _____ If eGFR is < 35, the hydration recommendations on page 5 are recommended.

1. Have you ever had an adverse reaction to a contrast agent, requiring the exam to be interrupted or medication to be administered? YES NO

Agent responsible for the adverse reaction: _____

If YES, the patient must take premedication (Preparation 1, page 5). If the responsible agent is unknown, an allergology consultation will be required (referral from your primary care physician) to determine the least reactive agent to use for the exam.

2. Do you suffer from any of the following diseases?

- Systemic or cutaneous mastocytosis (itching, hives, skin redness): YES NO
- Idiopathic anaphylaxis (hives, severe respiratory distress, acute asthma, or unexplained anaphylactic symptoms): YES NO

If YES to at least one question in section 2, premedication is required before the exam (Preparation 1, page 5).

Other allergies (molluscs, crustaceans, fish or other food, drugs and medicines, high-sensitivity to iodopovidone PVP-I) are not considered a risk factor for the administration of the contrast agent.

3. Do you have uncontrolled bronchial asthma, recurrent urticaria, or angioedema despite treatment?

Specifically, in the past 4 weeks, have you:

- Experienced asthma attacks more than twice a week: YES NO
- Woken up at night due to asthma: YES NO
- Used salbutamol (e.g., Ventolin) more than twice a week: YES NO
- Experienced limitations in daily activities due to asthma: YES NO
- Had episodes of urticaria or angioedema uncontrolled despite the use of antihistamines: YES NO

If YES to at least one question in section 3, consult your primary care physician to adjust your treatment. premedication is required before the exam (Preparation 2, page 5).

Location and Date: _____ Prescribing Physician's Signature: _____

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PATIENT SECTION

INFORMED CONSENT FOR CT SCAN WITH CONTRAST AGENT

I, the undersigned, _____

born on _____

DECLARE THAT

1. I have received clear and complete information about the procedure, its type, method, expected benefits, limitations, risks, and possible complications. I understand that in rare emergency situations (life-threatening), the procedure may be altered for life-saving purposes.
2. I am aware of my right to withdraw the current consent at any time before the CT scan.
3. I have been informed about the potential risks and benefits of the procedure and have freely and consciously decided whether to consent:
 ACCEPT **DECLINE**
4. I confirm that I have informed the radiologist about any confirmed or suspected pregnancy:
 NOT PREGNANT **PREGNANT**

Patient's Signature: _____

Radiologist's Signature: _____

FOR MINORS OR LEGALLY INCOMPETENT INDIVIDUALS

Legal Representative Information:

Name: _____ DOB: _____

Relation to Patient: _____

I DECLARE THAT

- I am the minor's parent and the other parent has been informed of the proposed procedure and gives consent (e.g., deceased, impediment, other).
- I am the sole legal representative of the minor or individual lacking decision-making capacity.
- I have received clear and complete information about the procedure.
- I ACCEPT** **I DECLINE** the examination for my child or minor.

Location and Date: _____ Legal Guardian's Signature: _____

Location and Date: _____ Parent's Signature _____

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FASTING: 6 hours prior to the exam (No food) 1 hour prior to the exam: No liquids.

ARRIVAL TIME: 30 minutes before the scheduled exam time; 90 minutes before if eGFR test is <35.

PREPARATIONS TO BE COMPLETED AT HOME (if recommended in the provided information) BEFORE THE IODINATED CONTRAST-ENHANCED EXAM:

➤ PREPARATION 1

Contact your primary care physician. Oral premedication:

- Prednisone 50 mg (or Methylprednisolone 32 mg), 12 hours before the exam.
- Prednisone 50 mg (or Methylprednisolone 32 mg), 2 hours before the exam.
- Antihistamine (e.g., Cetirizine) 1 hour before the exam.

OR

Intramuscular premedication:

- Prednisone 50 mg (or Methylprednisolone 32 mg), 12 hours before the exam.
- Prednisone 50 mg (or Methylprednisolone 32 mg), 2 hours before the exam.
- Chlorphenamine 10 mg, 1 hour before the exam, with the addition of Montelukast 10 mg.

NB: In cases of previous anaphylaxis, vital signs will be monitored during the procedure, and the anaesthesiologist will be alerted.

➤ PREPARATION 2

Contact your primary care physician. Oral premedication:

- Prednisone 50 mg (or Methylprednisolone 32 mg), 13 hours before the exam.
- Prednisone 50 mg (or Methylprednisolone 32 mg), 7 hours before the exam.
- Prednisone 50 mg (or Methylprednisolone 32 mg), 1 hour before the exam.
- Antihistamine (e.g., Cetirizine), 1 hour before the exam.

OR

Intramuscular premedication:

- Prednisone 50 mg (or Methylprednisolone 32 mg), 13 hours before the exam.
- Prednisone 50 mg (or Methylprednisolone 32 mg), 7 hours before the exam.
- Prednisone 50 mg (or Methylprednisolone 32 mg), 1 hour before the exam.
- Chlorphenamine 10 mg, 1 hour before the exam.

➤ PREPARATION 3

Preparation conducted and managed at the healthcare facility.

Rapid premedication via intravenous route: Bolus of Hydrocortisone 200 mg + Chlorphenamine 10 mg immediately before the exam. Vital signs will be monitored during the procedure and the anaesthesiologist will be alerted.

HYDRATION INSTRUCTIONS FOR HOSPITALIZED PATIENTS:

Intravenous administration in the ward:

- Sodium Bicarbonate (NaBic) 1.4%: 3 ml/Kg/hour 1 hour before the contrast agent administration.

OR

Physiological solution: 1 ml/Kg/hour for 3-4 hours before and 4-6 hours after the contrast agent administration.