

INFORMATION AND CONSENT FOR CARRYING OUT THE MAGNETIC RESONANCE EXAMINATION WITH CONTRAST MEDIUM

Date _____

The patient

LAST AND FIRST NAME	
Place of birth	
Date of birth	

OR: For the patient indicated above, the undersigned

LAST NAME			
FIRST NAME			
Place of birth	Prov.		
Date of birth		Fiscal Code	

As

parent caregiver legal guardian (other) _____

DEFINITION

The Magnetic Resonance (MRI) is a diagnostic technique that does not use ionizing radiation or radioactive substances. MRI diagnostics uses static fields of magnetic induction and radio frequency (RF) electromagnetic waves, similar to radio and television waves. The basic MRI is a non-invasive diagnostic test and based on current knowledge, it does not involve significant biological effects on patients without contraindications and is carried out in accordance with safety regulations and standards.

However, it is advisable not to perform the MRI examination in female patients during the first trimester of pregnancy.

PURPOSE

The main purpose is the diagnosis of pathological conditions affecting the brain and spine, abdomen, pelvis, large vessels and the musculoskeletal system (joints, bone, soft tissues).

EXECUTION

Source: Società Italiana di Radiologia Medica e Interventistica (SIRM)
Società e Salute SPA Sede Legale Via Temperanza, 6 – 20127 Milano

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The exam is neither painful nor unpleasant. The patient is lying on a bed and in relation to the type of organ to be studied, the so-called "coils" (bands, helmet, plates, etc.) are positioned outside the body, shaped so as to adapt to the anatomical region to be studied, these do not they cause pain or discomfort by being placed on the outside of the body. During the examination, rhythmic noises of varying intensity caused by the normal operation of the device are audible.

POSSIBLE COMPLICATIONS

Rarely, mild disturbances such as feeling claustrophobic, warmth, itching, breathlessness, palpitations or feeling unwell may arise. In these cases it will be possible to warn the operators using the appropriate intercom present inside the machine.

NECESSARY PREPARATION - RECOMMENDATIONS

Before undergoing the MRI examination, patients must collaborate with the doctor in order to correctly complete a specific "anamnestic questionnaire" useful to exclude any possible contraindication to the examination itself.

The following is recommended:

- deposit any metal, ferromagnetic or magnetic media object (cell phones, coins, watches, keys, earrings, pins, jewelry, hair clips, magnetic cards, credit cards, etc) in the special box. - remove any dental prostheses and hearing aids.
- remove contact lenses or glasses.
- undress and wear the special disposable gown provided by the service staff.
- use the headphones or earplugs provided by the service staff.

It is recommended to avoid making-up and using hairspray as they can create artifacts that reduce image quality.

Throughout the examination it is necessary to maintain the maximum degree of immobility, breathing regularly. It is not necessary to interrupt any pharmacological therapies in progress (eg. for hypertension or diabetes).

ANAMNESTIC QUESTIONNAIRE RMI

The "anamnestic questionnaire" is intended to ascertain the absence of contraindications to the examination and must be carefully filled out and signed at the bottom by the doctor in charge of the examination who, for his evaluations, also makes use of the answers provided by the patient or legal guardian (for example in the case of a minor).

YES	NO	Have you previously performed	YES	NO	Do you suffer from claustrophobia??
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		MRI exams?			
YES	NO	Have you ever worked (or do you work) as welder, turner, coachbuilder?	YES	NO	Have you ever been involved in a car accident, in a hunting accident?
YES	NO	Have you been a victim of blast trauma?	YES	NO	Are you pregnant or presumed to be pregnant?
YES	NO	Have you ever had allergic reactions after contrast medium?	YES	NO	Did you undergo surgery?

Head _____
 Abdomen _____ Neck _____
 Extremities _____ Chest _____ Eyes _____
 Other _____

Are you a bearer of:

YES	NO	Cardiac Pace-Maker or other types of cardiac catheters?	YES	NO	Metal splinters or fragments?
YES	NO	Clips on aneurysms (blood vessels), aorta, brain?	YES	NO	Heart valves?
YES	NO	Stents?	YES	NO	Implanted Defibrillators?
YES	NO	Do you have diabetes?	YES	NO	Infusion pump for insulin or other drugs?
			YES	NO	Intrauterine Device (IUD)?
YES	NO	Spinal or ventricular shunts?	YES	NO	Fixed or mobile dental prostheses?
YES	NO	Metal prostheses (for previous fractures, etc.), screws, nails, wire, etc...?	YES	NO	Other prostheses? Location _____
YES	NO	Do you think you can have prostheses / appliances or other metal bodies inside the body of which you may NOT be aware of?	YES	NO	Do you have a lens prosthesis?
			YES	NO	Do you have a piercing? Location _____
YES	NO	Are you using medical plasters?			
YES	NO	Do you have tattoos? Location _____	YES	NO	Are you aware of having one or more medical devices or metal bodies inside your body?

YES NO Wearer of devices whose characteristics (manufacturer, type and date of system) and / or the safety magnetic compatibility are not known.

To carry out the MRI exam, it is necessary to remove:

contact lenses - hearing aids - dentures - temporary crowns - hernia belt - hair clips - clothespins - glasses - jewelry - watches - credit cards or other magnetic cards - pocket knives - money clips - coins - keys - hooks - snap buttons - metal buttons - pins - clothes with zippers - metal tweezers - metal staples - nail files - scissors - any other metal objects.

Before undergoing the examination, please remove any makeup.

INFORMED SUMMARY OF THE ADMINISTRATION OF THE CONTRAST MEDIUM IN THE RMI

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How to do it:

The administration of the contrast medium is an integral part of the MRI examination and, in some types of investigations, it is essential for a correct diagnosis. The characteristics of these drugs allow a safe administration, "while taking into account the generic risks of hypersensitivity, characteristic of each injectable formulation" (Circular of the Ministry of Health 900.VI/11.AG./642 of 17.9.97).

Patients must first perform the blood CREATININE dosage and the calculation of the glomerular filtrate (max 1 month) and present it to the medical staff of the MRI section in order to evaluate its renal function. In fact, patients with moderate and severe renal insufficiency to whom a Gadolinium-based contrast medium is administered intravenously are at increased risk of developing a rare disease known as Nephrogenic Systemic Fibrosis (NFS). NFS is a rare disease characterized by debilitating and potentially fatal thickening of the skin and connective tissues.

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Based on recent evidence in the literature, the use of Gadolinium-based contrast medium in patients considered to be at high risk, in dialysis patients and / or undergoing renal transplantation, is closely linked to a conscious and shared choice between the requesting clinician and radiologist, respecting the lower biological cost and better diagnostic response.

The administration of the contrast medium can sometimes lead to some mild side effects (sensation of heat, redness, nausea, vomiting, headache, rash, itching) that an unpredictable and quantifiable but still very low incidence, can also induce severe allergic reactions up to anaphylactic shock. **It is therefore necessary to notify the Doctor in charge of the examination of any type of allergy before the examination itself.**

The health personnel of the Operating Unit are always present inside the structure to ensure prompt intervention in the event of an emergency.

The use of Gadolinium in pregnant women requires an assessment of the risk/benefit ratio. (Xagena2003) Source: UCSF (University of California San Francisco), **therefore any state of pregnancy must be previously communicated to the Doctor in charge of the MRI examination.** In this regard, we inform you that low-dose Gd-chelated contrast agents do not create problems.

It is also advisable to communicate the possible breastfeeding phase of your child to agree on any modalities and interruption times in relation to the MRI exam.

Any clarification regarding the execution of the MRI examination with a contrast agent can be requested to the staff of the Operating Unit.

Having acknowledged the information provided in the consent form, the patient may ask the radiologist for further explanations.

To perform an **examination with the use of contrast medium, it is necessary to have fasted for at least 6 hours (with the exclusion of drugs usually taken that can be ingested with water).** In case of carrying out tests with contrast medium it is essential to warn in advance of important known allergies, asthmatic conditions.

EXPRESSION AND ACQUISITION OF INFORMED CONSENT / DISSENT TO THE EXECUTION OF THE MRI INVESTIGATION WITH CONTRAST MEDIUM

The undersigned _____
in the case of a minor, the parent or guardian.

Informed:

on the type of diagnostic investigation to be performed and precisely Arthro Magnetic Resonance with intra-articular contrast medium

Made aware:

of the opinion of the healthcare professional that the proposed treatment is the one that offers the best risk/benefit ratio on the basis of current knowledge;

of the possibility that the investigation, once started, can be interrupted at my request, without prejudice to the assistance activity, but without obtaining the information sought with this examination;

the relative risks of any damage to health (temporary and permanent) and to life.

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Having read the information relating to the investigation / procedure in question

Having evaluated the information received and the clarifications that have been provided to me, having understood what is briefly reported above:

I ACCEPT the proposed investigation **I DO NOT ACCEPT the proposed investigation**

THE RADIOLOGIST

Having acknowledged the answers provided by the patient and completed any medical examination and / or further preliminary diagnostic investigations

AUTHORIZES THE EXECUTION OF THE MAGNETIC RESONANCE WITH CONTRAST MEDIUM

Signature of the Radiologist _____

DECLARATION OF CERTAIN OR PRESUMED PREGNANCY

YES **NO**

Signature of the patient _____

NOTICE OF ALLERGIES

1- to contrast medium: **YES** **NO**

2- allergies with previous episodes of respiratory failure, severe generalized urticarial manifestations, angioedema, bronchoconstriction, anaphylactic shock, loss of consciousness

YES **NO**

3- drug allergies **YES** **NO**

CAN I CHANGE MY DECISION REGARDING THE EXECUTION OF THE EXAM?

You are absolutely not obliged to carry out the examination; alternatively, the doctor will use other procedures that are currently available for which his consent will still be required.

Thank you for your attention in reading these notes. Please date and sign this form for acknowledgement.

Date _____ Patient's signature _____