

Please fill out with printed capital letters.

Name:

Mothers' name:

Date of birth:

SSN:

Information and consent form on MR scanning

— Dear Patients,

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

— General information

The MR (Magnetic Resonance) imaging examination is a modern procedure of the modern imaging diagnostics. During this, images are taken of the examined organs or the given parts of the body in strong magnetic field in various planes. The method can indicate the pathological lesions with great accuracy. The procedure does not involve radiation load. According to our current knowledge, even the repeated examinations do not endanger the person examined, therefore it has no adverse health effect.

Your practitioner and the examining radiologist should always consult on MR scanning or intravenous administering of MR contrast agent during pregnancy and breastfeeding!

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

— What to do before the examination

Regarding that the measurements are done using radio frequency waves in magnetic field, those patients with a pacemaker implanted cannot have the examination performed. Any items containing magnetizable material (iron, steel) may dislodge in the magnetic field, causing severe or even life-threatening injury or resulting in unassessable scan. If you have such or similar devices in your body (for example: hip or other joint prosthesis, nail, screw, metallic valve, neuro or vascular surgical tourniquet, etc.) always notify the doctor conducting the examination or the examining operator! Any metallic object worn on your body (hearing aid, watch, chain, metal hairpin, body jewels, denture, etc.) must be taken off, your pockets (coins, keys, pen, credit card, phone, etc.) must be emptied and the contents placed in the locker in the changing room. Objects operating with electricity or containing magnetic parts may be damaged in the strong magnetic field, we cannot take responsibility for them! If you have any cosmetic containing metal (glitter eye shadow, face powder, etc.), it must be removed before entering the examination room because they may render the examination unassessable. The medicines that you take regularly, must also be taken on the day of the examination with water. In the days before the examination, consume ample quantity of fluid (2-3 litres). If the examination takes place at noon or in the evening hours, consume fluid also on the day of the examination! Do not eat 4 hours prior to the examination but consume fluid (water)! If you are given intravenous contrast agent during the examination, then consume ample fluid also on the 2-3 days following the examination!

— Examination procedure

The duration of the examination is 15-40 minutes. The examination takes place in lying posture and involves no pain. Its drawback is that the patient has to lie in a relatively confined space which may induce feeling of confinement. During the examination, strange machine noises can be heard.

If this noise is disturbing for you, ask for earplugs from the operator. If you are afraid or feel anxiety, you can talk to the assistant via microphone.

You can talk to the person conducting the examination via loudspeaker and call her/him at any time with the help of an emergency alarm system. Do not move during the examination, you shall lie in the posture set by the operator. In case of chest and abdominal scans, breath must be held, the scan operator will instruct you so via microphone. The individual measurements are ready within 2-7 minutes.

In case of MR small intestine, gastric-pelvic or pelvic MR examinations, the reducing of bowel movements is done with smooth muscle antispasmodic injection. The effect of the drug lasts for 10-15 minutes, will not cause sleepiness.

— Possible hazards, adverse effect and their avoidance and prevention

If more accurate image is to be obtained on the function an organ or the deviation within the organ, intravenous paramagnetic contrast agent is to be injected which is prescribed by professional recommendations. This is usually introduced into the body through the brachial vein.

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In case of contrast agent MR 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.

Contrast agent hypersensitivity (allergy) occurs rarely. Symptoms: swelling of face, lips, tongue, throat, coughing, itching, nose running, sneezing, urticaria, dyspnoea, 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! The allergy may be mild, in rare cases, severe. It is extremely rare to have anaphylactic (hypersensitivity) shock state which, in extreme cases, may lead in to circulatory collapse and cardiac arrest. Our institute is equipped and prepared to prevent a possible allergic reaction, the necessary clinical background is available. If you are suffering from renal insufficiency, the paramagnetic contrast agents may cause cicatrization affecting kidneys or even the whole body (NSF - Nephrogenic Systemic Fibrosis). To avoid this, please read carefully the questionnaire on the next page and provide accurate answers to the questions. If you have more than one risk factors, the knowledge of the laboratory tests results on the renal function is important in order to avoid a possible renal impairment.

The effect of the smooth muscle antispasmodic injection 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). 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 in your eyes, immediately consult an ophthalmologist because a latent disease may exist in the background!

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 MR scanning and the contrast agent MR 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.

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.

Do you have hypersensitivity to any kind of medicine?

Yes No

Have you been administered MR contrast medium before?

Yes No

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

Yes No

Do you have asthma?

Yes No

Do you have any kind of kidney (renal) disease?

Yes No

Do you have a high blood pressure?

Yes No

Do you have a diabetes?

Yes No

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

Yes No

Are you currently breastfeeding?

Yes No

Do you wear an intrauterine contraceptive device (IUD)?

Yes No

Do you have any other significant diseases?

Yes No

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Other significant disease

Height (cm)

Body weight (kg)

If you wear any metallic objects on your body, or you have an implanted metallic device, etc. please inform the operator performing your examination or the doctor who oversees it. If you have any questions regarding the procedure, please ask the doctor or the operator performing your examination. **We cannot take responsibility for any damage to an object you carry, or if such object causes an injury to you during your examination.**

Do you wear metal/foreign material in or on your body, or an electrical device??

- Yes, I do
 No, I do not

If yes, in/on which body part?

- Cranium
 Chest
 Abdomen
 Pelvis
 Extremities

Type of metal/foreign material:

- Stent
 Cardiac pacemaker
 Aorto-coronary bypass
 Artificial heart valve
 Surgical plates
 Aneurysmal clips
 Replacement of joint(s)
 Eye, ear or dental implant
 Body piercing
 Tattoos or tattooed liner
 Magnetic cosmetics and hair care (e.g. magnetic eyelashes, magnetic nail polish)
 Any other metal fragments: _____

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 MR 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)

Please fill out with printed capital letters.

Name:

Mother's name:

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 legibly, printed letters.)

Date of signing the consent form