

Clinic/Practice

Radiologisches Zentrum Lahnstein MVZ GmbH  
Südallee 19 - 21  
56112 Lahnstein

## Computed Tomography (CT)

Patient's Name and Address

Vorname Nachname

Anschrift

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Fall-ID / Geburtsdatum / Patienten-ID

/

Krankenkasse / Versicherungsnummer

Dear \_\_\_\_\_, Dear Parents,

The purpose of this informed consent form is to help you prepare for the patient-doctor discussion. Please read it carefully before the discussion and complete the questionnaire carefully and completely. For better readability, we use male pronouns but are addressing all genders with them.

### Which examination is proposed?

Computed tomography is planned for you. This imaging procedure provides cross-sectional images of any chosen body region. Using these CT images (computed tomographs), the location and extent of a possible disease or injury can generally be determined more accurately than with regular X-ray images. Therefore, they are also a significant help in planning operations, radiation and other treatments.

### Are there any alternative forms of examination?

If e.g. an ultrasound examination, magnetic resonance imaging, X-ray examination with or without contrast medium, nuclear medicine examination, a contrast enema or endoscopy (e.g. colonoscopy) is an alternative to computed tomography, the doctor will provide you with details about these alternatives and their advantages and disadvantages, the demands they place on the body, risks and chances of success in the patient-doctor discussion.

### How is computed tomography performed?

You will be positioned on an examination table that will be moved into the round opening of the CT scanner (gantry) and placed in such a way that you will be in the correct position for the examination. For the protection of organs which are not to be examined and exposed to radiation, suitable protective measures and positioning aids will be

used. An X-ray tube with a measurement system then rotates around your body. Please lie completely still and relaxed during the examination. You will possibly receive breathing instructions via a loudspeaker. Within seconds, the computer calculates cross-sectional images from the acquired data.

To improve the informative value of the images, you can receive a contrast media solution or water to drink up to 2 hours prior to the examination. For certain issues, it is required to inject a contrast medium into a vein in addition. For the visualisation of the large intestine, it is possibly required to fill it with contrast media or water using a rectal tube and with air or carbon dioxide for a "virtual colonoscopy" (replaces the endoscopic colonoscopy). The administration of a medication to immobilise the intestine (e.g. Buscopan®) may be required. If those measures are proposed in your case, your doctor will provide you with information about them.

### Risks and possible associated complications

Despite all the care taken, complications can arise which can become life-threatening under certain circumstances

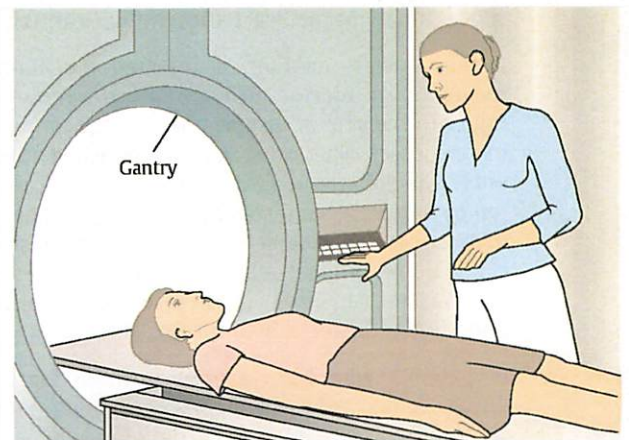


Fig.: Possible positioning for computed tomography



and require additional treatment/operations. The frequency rates are only a general estimate and are intended for weighing the risks against each other. They are not the same as the definitions of side-effects stated in the package inserts of medications. Pre-existing/underlying diseases and individual unusual circumstances can significantly influence the rate of complications.

- You will be **exposed to X-ray radiation** in the proposed computed tomography. However, the radiation dosage is so low that there is no risk of direct damage (e.g. to the skin or organs) by the radiation. Only the risk of the occurrence of cancer after several years or decades can be increased minimally. Therefore, the indication for this examination will only be issued by a doctor with the required qualification, and only if the chance of obtaining more information clearly exceeds the low radiation risk. In particular, the doctor will thoroughly consider the indication for examinations in which an unborn child could be exposed to a higher dose of X-ray radiation if the patient is pregnant. Should you have any questions, please do not hesitate to ask the doctor carrying out the examination for further information.
- If Buscopan® or another medication is injected, **temporary dryness of the mouth**, an **accelerated heart rate** or visual impairment can occur. In extremely rare cases, an **acute attack of glaucoma** (increase of the intraocular pressure) occurs if non-treated glaucoma is present. In men, **retention of urine can occur after the examination**, which will resolve again.
- Upon injection of the contrast medium into the blood stream, the patient may experience a **short-term warm sensation and an irregular heart rate**.
- A **haematoma**, which goes away by itself in most cases, and also **local hardening or discolouration of the skin** can occur at the puncture site. **Skin/tissue/nerve damage** at the puncture site or due to measures that may be needed in conjunction with the procedure (e.g. infusions) is rare. Side-effects/complications that can be permanent under certain circumstances: pain, inflammation, necrosis (death) of tissue, venous irritation/inflammation, scars and disorders of sensation and dysfunction, paralysis (e.g. of the extremities).
- **Infection** is rare. In very rare cases, **life-threatening generalised blood poisoning (sepsis)** due to the spread of pathogenic micro-organisms can occur, which necessitates inpatient medical treatment with antibiotics.
- If the contrast medium is **injected mechanically** by means of an injector through an intravenous cannula, injury to the vein or displacement of the cannula occurs in rare cases. This can cause the **contrast medium to enter the soft tissue (extravasation)**; this can be treated by a massage and subsequent compression dressing in most cases. A greater leakage of the contrast medium can require surgical relief in very rare cases. Smaller extravasates can also occur in rare cases if contrast medium is administered by **infusion**.
- In patients who have a predisposition for this condition, X-ray contrast media containing iodine can cause **overactivity of the thyroid gland** (hyperthyroidism), which can necessitate treatment with medications under certain circumstances. Furthermore, temporary **blood pressure fluctuations or disorders of the kidney function** can occur which go unnoticed in most cases. **Permanent kidney damage** which could necessitate di-

alysis occurs rarely, even in cases in which kidney damage is already present.

- **Allergy/hypersensitivity/incompatibility** (e.g. to the contrast medium, medications, disinfectants, latex) can cause an acute circulatory shock, necessitating intensive care. **Severe damage** (e.g. organ failure, brain damage, paralysis), which can be permanent under certain circumstances, is very rare. Mild allergic reactions can cause e.g. temporary swelling, itching, sneezing, skin rash, dizziness or vomiting.
- In very rare cases, **injury to the intestine (perforation)** occurs as a result of introducing air and/or water. This can cause **inflammation of the membrane lining the abdominal cavity (peritonitis)**, which can be life-threatening under certain circumstances and which is to be treated by medications (e.g. with antibiotics) or in an operation. In very rare cases, a stoma, which is usually only temporary, must be placed.
- **Diarrhoea (in some cases sudden and very severe!), flatulence (gas), cramps, nausea or other symptoms** can occur if a contrast medium is taken orally. These symptoms go away by themselves. **Nausea and vomiting** can also occur after the injection of a contrast medium into the blood stream.
- The risk of developing a **cataract (opacity of the lens of the eye)** is slightly increased in patients who have had several repeated examinations of the brain.

## Instructions

### Before the examination

Please provide any **existing medical identification/records** (e.g. Marcumar, allergy, pacemaker/implant, diabetes card or X-ray card, etc.).

If applicable, please bring all previous X-ray images, computed tomography, magnetic resonance images/findings and findings of ultrasound examinations pertaining to the relevant body region to the appointment.

If you need to bring blood test results (e.g. creatinine, TSH levels) for the examination, your doctor will inform you about it.

Please list **all medications** that you are taking in the questionnaire (also herbal remedies and over-the-counter medications). The doctor treating you will then decide if and when these medications should be stopped or replaced by another medication. In particular, they include medications containing the active substance metformin in the case of patients who have diabetes.

If the examination requires a **contrast medium injection**, **sufficient fluid should be consumed on the day prior to the examination** to reduce the risk of kidney damage due to the contrast medium. Therefore, please drink plenty of clear fluids (e.g. tea, mineral water) **on the previous day**; do not drink milk or alcohol. If necessary, fluids can also be administered as an infusion via a venous catheter. Your doctor will tell you if you also need to drink plenty of fluids on the day of the procedure itself.

**Please do not eat anything** for at least **4 hours** before the examination appointment and **do not smoke**. If examination of the **abdominal cavity** is planned, do not eat anything that could cause gas **on the day before the examination**.

### After an examination with contrast media

After the intravenous administration of a contrast medium, you should drink plenty of fluids (e.g. tea, mineral

water, juice) but no milk or alcohol, so that the contrast medium can be passed more quickly.

If you received **Buscopan®**, your vision can be temporarily impaired. Therefore, you have to be picked up by an adult, or you will be monitored for some time after the examination. In particular, your doctor will inform you about how long your ability to participate in road traffic and operate machines will be impaired.

If you experience any symptoms (e.g. nausea, diarrhoea, feeling of sickness, dizziness, sneezing, skin rash, pain, fever greater than 38 °C, chills), immediately consult a doctor, even if these symptoms only occur a few days after the examination!



Vorname Nachname

Anschrift

Fall-ID / Geburtsdatum / Patienten-ID

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## Questionnaire (patient history)

Please answer the following questions carefully and completely to aid us in avoiding all possible risks. Please mark boxes where applicable and underline or add text where appropriate. If necessary, do not hesitate to ask for our assistance in filling out the form. **For the patient's guardian, custodian, legal representative:** Please answer all questions from the patient's viewpoint.

Age: \_\_\_\_\_ years • Height: \_\_\_\_\_ cm • Weight: \_\_\_\_\_ kg

Gender: \_\_\_\_\_

n = no/y = yes

1. Are you taking any medications (e.g. anticoagulant medications [e.g. Marcumar®, Aspirin], pain medications, antidiabetics [especially any medications containing metformin], cardiovascular agents, hormone preparations, sleeping pills or sedatives, anti-hypertensive medications)?  n  y

If yes, please indicate! \_\_\_\_\_

2. Do you have or have you ever had (another) cardiovascular disease (e.g. coronary heart disease, hypertension, cardiac arrhythmia, stroke, heart attack, angina pectoris, myocardial inflammation, heart valve defect)?  n  y

If yes, please indicate! \_\_\_\_\_

3. Do you have any implants (e.g. cardiac pacemaker, defibrillator, cardiac valve, stent, artificial joint, silicone, hydrogel, teeth, metal)?  n  y

If yes, please indicate! \_\_\_\_\_

4. Do you have or have you ever had any disease or malformation of the kidneys/urinary organs (e.g. dysfunction of the kidneys, kidney stones, chronic urinary tract infection, nephritis/inflammation of the kidneys, congenital malformation [e.g. duplex kidney], bladder emptying disorder/delayed bladder emptying)?  n  y

If yes, please indicate! \_\_\_\_\_

5. Do you have or have you ever had any diseases of the blood (e.g. anaemia, leukaemia, multiple myeloma)?  n  y

If yes, please indicate! \_\_\_\_\_

6. Do you have any metabolic diseases (e.g. diabetes, gout)?  n  y

If yes, please indicate! \_\_\_\_\_

7. Do you have or have you ever had any diseases of the thyroid gland (e.g. overactivity of the thyroid gland, underactivity of the thyroid gland, goitre, Hashimoto's)?  n  y

If yes, please indicate! \_\_\_\_\_

8. Is an examination, operation or radioactive iodine therapy of the thyroid gland planned for the near future?  n  y

9. Do you have any eye diseases (e.g. cataract, glaucoma)?  n  y

If yes, please indicate! \_\_\_\_\_

10. Do you have any allergies (e.g. medications [e.g. antibiotics, metamizole, paracetamol], anaesthetic agents, contrast medium, latex, disinfectants, iodine, plasters, synthetic material)?  n  y

If yes, please indicate! \_\_\_\_\_

11. Do you have or have you ever had an infectious disease (e.g. hepatitis, HIV/AIDS, meningitis, tuberculosis)?  n  y

If yes, please indicate! \_\_\_\_\_

12. Do you have or have you ever had any disorders of the digestive system (e.g. oesophagus, stomach, intestine)?  n  y

If yes, please indicate! \_\_\_\_\_

13. Do you have any disease in the anal region (e.g. haemorrhoids, constrictions, prolapse of the intestine, skin tags)?  n  y

If yes, please indicate! \_\_\_\_\_

14. Have you undergone any imaging procedures in the last 10 years (e.g. X-ray examination, computed tomography, magnetic resonance imaging)?  n  y

If yes, please indicate! \_\_\_\_\_

If yes, in which part of the body (e.g. upper body, abdomen, spine, head, extremities)? \_\_\_\_\_

If yes, please indicate the name of the clinic/practice! \_\_\_\_\_

15. Have you ever undergone an examination with contrast media?  n  y

If yes, did any complications occur (e.g. rash, cardiovascular reactions, shock)?  n  y

If yes, please indicate! \_\_\_\_\_

16. Have you ever had an operation of the body region to be examined?  n  y

If yes, please indicate! \_\_\_\_\_

## Additional questions for women

1. Could you possibly be pregnant?  n  y

2. Are you breastfeeding?  n  y

## Additional questions for men

1. Do you have or have you ever had any disease of the prostate (e.g. prostatic enlargement, prostatitis [inflammation of the prostate], prostate cancer)?  n  y

If yes, please indicate! \_\_\_\_\_

### Doctor's notes

I have informed the patient about the examination using the informed consent form at hand, discussing in particular the following aspects and individual unusual circumstances (e.g. individual risk profile; underlying diseases; alternative treatment methods; additional treatment measures; chances of success; instructions; special urgency or demands on the body; duration of the discussion; determination of a minor's ability to comprehend; patient has a legal surrogate decision-maker/a legal guardian; patient has appointed a legal representative/provided a medical power of attorney; information provided in response to the patient's questions, etc.):

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The following examination is proposed:  
**Computed tomography of**

\_\_\_\_\_

Please state the body region

with contrast medium if indicated

Proposed examination date: \_\_\_\_\_

Date

### In case of refusal to consent

I do not consent to the proposed examination. I was informed about the recommended examination and have been emphatically informed of the possible severe consequences (e.g. failure to diagnose a disease or injuries) involved in my refusal; therefore, an alternative treatment method should be chosen at least.

\_\_\_\_\_

Place, date, time

\_\_\_\_\_

Patient

\_\_\_\_\_

Patient's guardian\*

\_\_\_\_\_

Witness (if applicable)

\_\_\_\_\_

Doctor

### Statement of Consent

I have read the informed consent form, and I understand it. The above-named examination, its nature and significance, alternative examination methods, the risks and possible associated complications, chances of success, possibly necessary changes or additions to the procedure, and additional/subsequent procedures possibly required for medical reasons have been fully explained to me in a patient-doctor discussion with doctor \_\_\_\_\_.

My questions were answered completely and clearly.

I have **no further questions** and feel that the **counselling was satisfactory**; I do not need **any further time for consideration and consent** to the proposed examination. I also agree to any possibly unforeseeable changes in or additions to the procedure which may be necessary for medical reasons.

I will follow the doctor's instructions.

\_\_\_\_\_

Place, date, time

\_\_\_\_\_

Patient

\_\_\_\_\_

Patient's guardian\*

\_\_\_\_\_

Doctor

\* Only if the patient is a minor: If only one of the patient's guardians signs, with this signature, he confirms that he has sole custody of the child or that he is acting in agreement with the other of the patient's guardians. As a rule, both of the patient's guardians should sign for major procedures. Minor patients who are able to comprehend should also always sign.