1. MRI examination

The basis consists of a defined examination protocol, the native whole-body MRI. This protocol is supplemented by the modules cardio (heart) MRI, MR angiography in men and MR mammography in women. The use of a contrast agent containing gadolinium is required to perform the additional modules. Performing the additional modules is also associated with additional time expenditure for the subject.

1.1. Whole-body MRI examination protocol

The sequences of the whole-body protocol are described in the following table. The whole-body MRI protocol does not include the administration of an MRI contrast agent. It includes a comprehensive diagnosis of the skeletal system (including the spine), the head, the neck, the lungs and the abdomen. The whole-body protocol is performed in the supine position.

Body region	Sequence name **	TR in ms	TE in ms	SD in mm	Time in minutes
Localizer	GK_FastView	3:31	2:19	5	0:48
Whole body	gre_GK_3_5E_80S_MP	12	2.38 4.40 6.42 8.44 10.46	5	1:45
Whole body	GK_t2_tirm_cor_300_p2	4900	67	5	6:31
Spine	WS_T2_tse_sag	3760	106	4	2:04
Head	Kopf_T2_tse_tra	5930	102	5	1:42
Head	Kopf_T2_spc_irprep_tra_dark-fluid_p2	5000	325	3	3:47
Head	Kopf_T1_mpr_tra_iso_p2	1900	3:37	1	3:38
Head	Kopf_ep2d_diff_3scan_trace_p2	3000	89	5	0.59
Head	Kopf_T2_swi3d_tra_p2_fast	49	40	3	2:35
Head	Kopf_TOF_3d_multi_slab	23	7	0.7	3:23

Body region	Sequence name **	TR in ms	TE in ms	SD in mm	Time in minutes
Neck	Hals_T2_tse_tra_p2	7390	72	4	5:19
Thorax	Thorax_vibe_no-fs_tra_bh	3:05	1:12	3	0:21
Thorax	T2_haste_ tra_bh_p2	550	22	5	0:40
Abdomen	Oberbauch_T2_blade_fs_tra_ mbh_p2 Atemtriggerung	2720	116	6	1:16
Abdomen	MRCP_T2_tse3d_rst_cor_p2_ 384	957	622	1.5	1:42
Abdomen	Abdomen_T1_fl2d_fs_tra_mb h_ Abd	251	4:13	6	1:17
Abdomen	Gre_dixon_fatty Liver	12	2:38	3	0:19
Abdomen	Körperstamm_T1_vibe_tra_p2 _dixon	7:48	2:38	5	0:38
pevlis	Becken_pd_tse_fs_tra_384_p 2	3230	34	3	2:43

This program results in a total measuring time of 60-70 minutes under optimum conditions. Even if the pure measuring time is less than 60-70 minutes, the independent adjustment of the table and the insertion of the layers must be taken into account, for example. In the abdominal examination in particular, the measurement time is linked to the respiratory rate, so that this can vary by +/- 8 minutes from subject to subject.

1.2. Contrast agent administration – advantages, spectrum of side effects

The intravenous injection of a contrast agent containing gadolinium is essential for the examination of the additional modules. Without the administration of a defined bolus of contrast agent, it is not possible to draw conclusions about pathological processes in the breast tissue and the arterial vascular system. In the MRI heart module, the diagnostic value is increased by the detection of late enhancement. This method can be used to visualize infarct scars, among other things.

The SHIP study uses a uniformly clinically established, gadolinium-containing, extracellular gadolinium chelate. Gadovist® (Bayer-Schering AG) is an MRI contrast agent with comprehensive approval for all organ systems.

Gadovist®

- 1 ml solution for injection contains 604.72 mg gadobutrol (corresponding to 1.0 mmol gadobutrol or 157.25 mg gadolinium).

Physicochemical properties

- Osmolality at 37°C: 1603 mOsm/kg H2O
- Viscosity at 37°C: 4.96 mPa.s

Pharmaceutical form

- Solution for injection
- clear, colorless to slightly yellow liquid

Applications

- Contrast enhancement for whole-body MRI
- Contrast enhancement for cranial and spinal MRI
- Contrast-enhanced MRI of the liver and kidneys
- Contrast enhancement for MR angiography (CE-MRA)
- Contrast enhancement for MR mammography (CE-MRM)

Dosage, application

The required dose is administered intravenously as a bolus injection. The recommended dose for adults is 0.1 mmol per kilogram of body weight (mmol/kg bw). This corresponds to 0.1 ml/kg bw of the 1.0 M solution.

Contraindications

Hypersensitivity to the active substance or any of the other ingredients.

Side effects

Undesirable effects are "rare (<1/1,000)"

If the patient consents to the administration of a contrast agent as part of the additional modules cardio-MRI, MR angiography, MR mammography, a comprehensive allergy

history is taken. As the contrast medium is excreted via the kidneys, a functional impairment can hinder excretion. Functional efficiency is documented on the basis of GFR and serum creatinine.

Side effects are rare after intravenous injection of Gadovist®. However, the test person is fully informed about possible side effects.

Spectrum of side effects of Gadovist® as an approved medicinal product:

- Headache
- aching limbs
- Nausea, vomiting
- skin rash
- Circulatory decompensation
- Anaphylactic shock

1.3. MRI cardio-mammary examination protocol

1.3.1. Implementation of the MRI cardio-mammary modul

The MRI cardio-mammary module is performed exclusively on women for reasons of safety. The protocol is based on the clinically used sequences. For technical reasons (application of the breast coil), the subject must be repositioned in the prone position after the whole-body and native cardio MRI. In order to be able to examine the heart after contrast medium administration, the patient must be repositioned after the breast MRI. The contrast agent series of the heart (delayed enhancement) can then be performed.

1.3.1.1. Cardio MRI examination protocol

Sequence name **	TR in ms	TE in ms	SD in mm	Time in minutes
trufi_loc_multi_iPAT@ _c	285:16	1:14	8	0:11
trufi_2_chamber_iPAT	253:6	1:14	8	0:08
trufi_4_chamber –iPAT	268:72	1:21	8	0:08
trufi _short_ axis _ iPAT	268:72	1:21	8	0:63
tf_2d7_retro_iPAT_4CV	18:55	1:12	6	0:60
tf_2d7_retro_iPAT_3CV	18:55	1:12	6	0:10
tf_2d7_retro_iPAT_2CV	18:55	1:12	6	0:60

tf_2d22_retro_sax_TR_4	44:96	1:20	6	0:54
tf_2d22_retro_RV_tra	56:20	1:18	6	1:17
Contrast agent series				
trufi_loc_multi_iPAT@ _c	285:16	1:14	8	0:11
TI-Scout	21:87	1:03	8	0:15
tfi_single_shot_12sl_bh	809:60	1:04	10	0:35
tfi_psir_single_shot_12sl	755:00	1:03	10	0:35

1.3.1.2. MRI breast examination protocol

Sequence name	TR in ms	TE in ms	SD in mm	Time in minutes
Localizer	7:1	3:32	6	0:12
TIRM tra	5800	56	6	3:01
T2 tse tra	4660	67	4	3:17
GADOVIST®	0,1 ml/kg/KGX 1,0		flow 2 ml/Sek;	20 ml phys. NaCl
TWIST-Dynamik	8:86	4:51	1,5	7:03

1.4. Cardio-MRI/MR angiography examination protocol

1.4.1. MRI heart protocol

Sequence name**	TR in ms	TE in ms	SD in mm	Time in minutes
trufi_loc_multi_iPAT@ _c	285:16	1:14	8	0:11
trufi_2_chamber_iPAT	253:6	1:14	8	0:08
trufi_4_chamber –iPAT	268:72	1:21	8	0:08
trufi _short_ axis _ iPAT	268:72	1:21	8	0:63
tf_2d7_retro_iPAT_4CV	18:55	1:12	6	0:60
tf_2d7_retro_iPAT_3CV	18:55	1:12	6	0:10
tf_2d7_retro_iPAT_2CV	18:55	1:12	6	0:60
tf_2d22_retro_sax_TR_44	44:96	1:20	6	0:54
tf_2d22_retro_RV_tra	56:20	1:18	6	1:17
Contrast agent series				
trufi_loc_multi_iPAT@ _c	285:16	1:14	8	0:11

TI-Scout	21:87	1:03	8	0:15
tfi_single_shot_12sl_bh	809:60	1:04	10	0:35
tfi_psir_single_shot_12sl	755:00	1:03	10	0:35

After all sequences for the additional heart module have been completed, we calculate a total measurement time, including delayed enhancement, of 18 minutes - under optimal conditions. The heart contraction is linked to the measurement time of the heart rate, so that this can vary from subject to subject (+/- 8 minutes).

1.4.2. MR angiography protocol

MR angiography is only performed in men following the whole-body MRI protocol. It is not necessary to reposition the subject. The examination is performed in the supine position, head first. MR angiography is performed in combination with the MRI heart protocol. A time of approx. 10 minutes is scheduled for the MR angiography.

Sequence name**	TR in ms	TE in ms	SD in mm	Time in minutes
1. Localizer				
IV_trufisp_head	3:67	1:84	7	0:19
III_trufisp_abdomen	3:67	1:84	7	0:17
II_trufisp_legs	3:67	1:84	7	0:17
I_trufisp_feet	3:67	1:84	7	0:17
2. Native series				
I_fl3d_cor_feet_pre	2:55	0:90	1,5	0:16
II_fl3d_cor_legs_pre	2:48	0:90	1,5	0:12
III_fl3d_cor_abdomen_pre	2:48	0:90	1,5	0:12
IV_fl3d_cor_head_pre	2:48	0:90	1,5	0:11
GADOVIST®	0,1 ml/kg/KG X 1,5		flow 2 ml/sek;	20 ml phys. NaCl
IV_care_bolus_cor	33:54	1,19	18	1:29
3. Contrast agent series				
IV_fl3d_cor_head_post	2:48	0:09	1,5	0:11
III_fl3d_cor_abdomen_post	2:48	0:09	1,5	0:12
II_fl3d_cor_legs_post	2:48	0:09	1,5	0:12
I_fl3d_cor_feet_post	2:55	0:09	1,5	0:16

Abdomen_T1_fl2d_fs_tra_ mbh_ Abd_KM	251	4:13	6	1:17