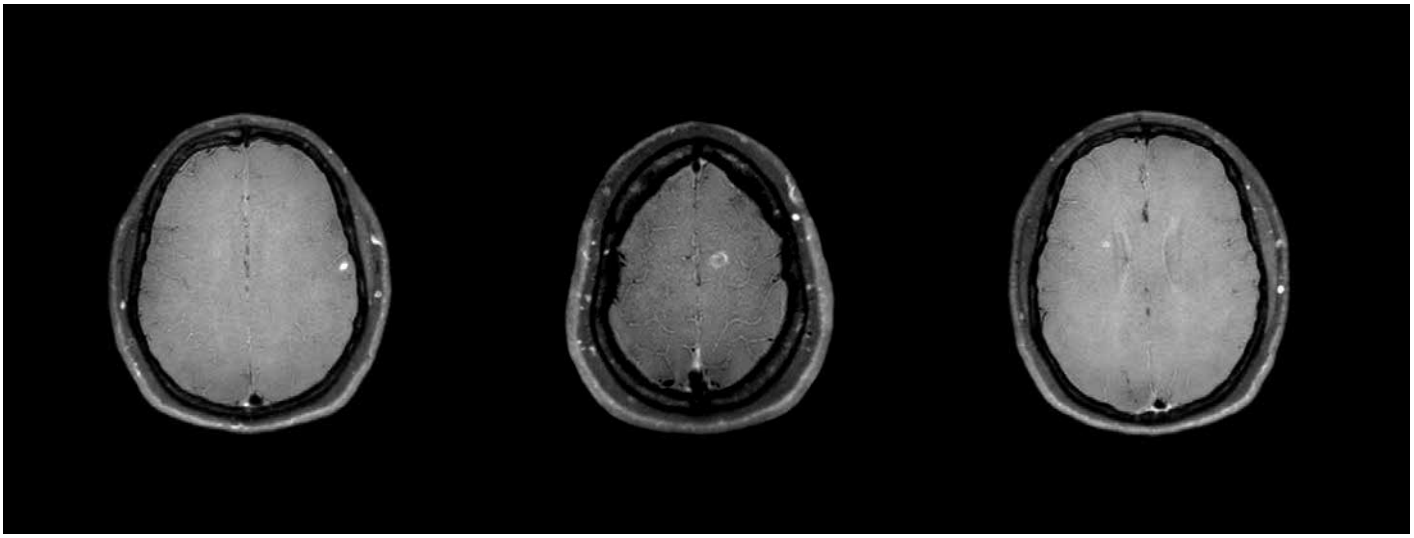
GE HealthCare

CASE STUDY

MRI of the central nervous system (CNS)



Images and content are courtesy of:
Prof. Dr. Johannes Pfaff, MHBA
Department of Neuroradiology
Christian Doppler Clinic
University Hospital Salzburg, Austria

CASE STUDY

MRI of the central nervous system (CNS)

Medical history of the patient

Patient in her late 20s presented to the ophthalmology department with right-side blurry vision and pain associated with eye movement starting 5 days previously. Additionally, right peri-orbital pain was noticed by the patient 2 days after the first symptoms occurred. No specific risk factors associated with smoking or substance abuse; no previous drug treatment or history of pain.

Preliminary diagnostics

The initial ophthalmological examination showed papilloedema and a partial central scotoma of the right eye. The patient's visual acuity on the right eye was 0.40, respectively 1.0 on the left eye.
The neurological examination showed no further abnormalities.
A non contrast-enhanced computed tomography of the brain did not show signs of an acute ischaemic stroke, intracranial haemorrhage, an intraorbital or intracranial mass. A lumbar puncture was performed to collect cerebrospinal fluid. The results of this laboratory test were still pending at the time of the MRI examination. The patient was placed on intravenous methylprednisolone in the emergency room.

Indication for MRI

The indication for magnetic resonance imaging was to exclude or confirm the presence of intracranial hypertension or changes consistent with a chronic inflammatory demyelinating disease of the central nervous system. The requested examination was the patient's first MRI examination.

Scan protocol includes

MRI: 3T

1. Coronal T2 SPIR
2. Axial contrast-enhanced (CE) 3D T1 GE
3. Axial CE 3D T1 GE black blood
4. Coronal CE 3D T1 GE black blood
5. Axial T2w FLAIR

Injection protocol

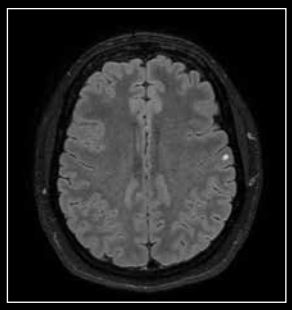
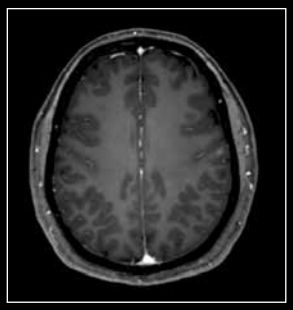
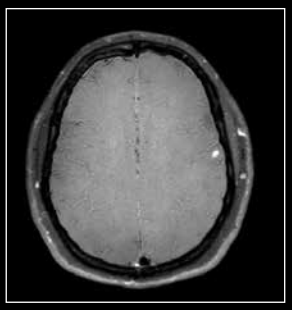
Patient weight 145 kg

GBCA injection	
Pixxoscan™ (gadobutrol) 0.1 mmol/kg	14.5 mL
0.9 % NaCl	10mL
Administration mode	Manual

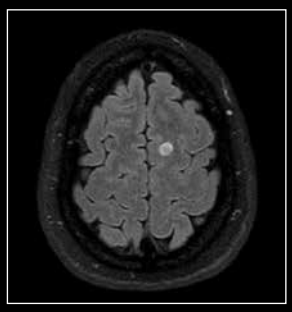
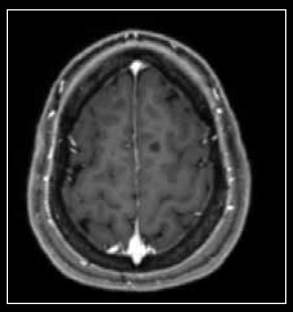
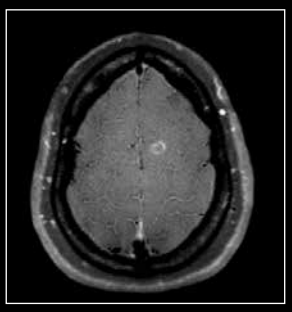
Please refer to the full Product Monograph before prescribing.

Findings of the MRI examination

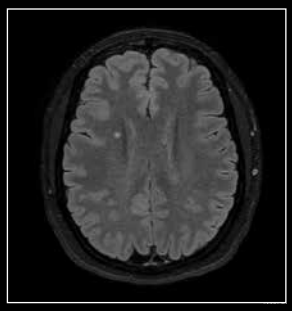
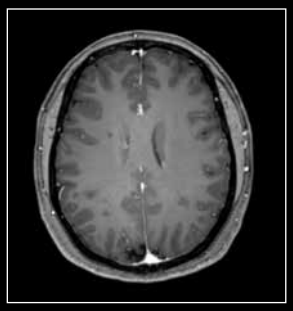
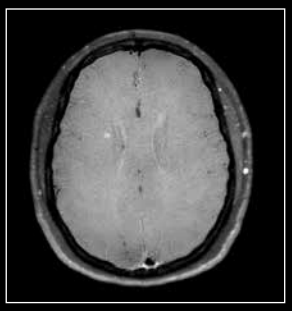
On the MRI images, presence of 3 specific FLAIR/T2w hyperintense lesions with individual contrast enhancement, and of a right-sided optic neuritis. An additional T2 hyperintense, non contrast-enhancing lesion in the occipital periventricular white matter can be seen on the axial FLAIR sequence.

Axial T2w FLAIR	Conventional axial CE 3D T1w	Black blood axial CE 3D T1w
		

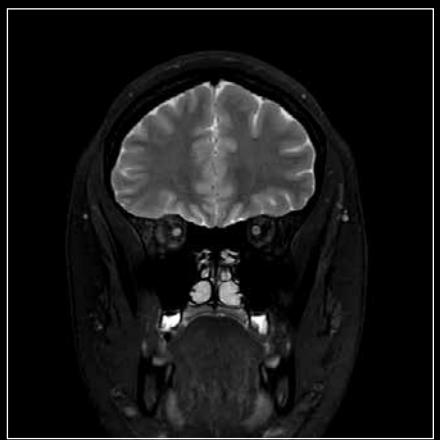
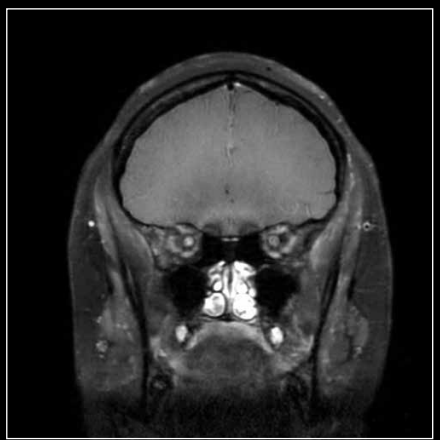
Axial T2w FLAIR, conventional CE 3D T1w, CE 3D T1w black blood sequences:
Showing a subcortical hyperintense (on the T2w FLAIR sequence), contrast-enhancing white matter lesion located in the left inferior fronto-temporal gyrus.
Please note that the contrast enhancement in the 3D T1w black blood sequence is much clearer than in the conventional 3D T1w sequence.

Axial T2w FLAIR, conventional CE 3D T1w, CE 3D T1w black blood sequences:
Showing a hyperintense (on the T2w FLAIR sequence), incomplete ring contrast-enhancing white matter lesion located in the left superior fronto-temporal gyrus.
Please note that the contrast enhancement in the conventional 3D T1w sequence is not visible, but very well visible in the 3D T1w black blood sequence.

Axial T2w FLAR, conventional CE 3D T1w, CE 3D T1w black blood sequences:
Showing a hyperintense (on the T2w FLAIR sequence), incomplete ring contrast-enhancing lesion located in the right frontal periventricular white matter
Please note that the contrast enhancement in the conventional 3D T1 weighted sequence is not visible, but subtle enhancement can be seen in the 3D T1w black blood sequence.

Coronal T2w SPIR	Coronal black blood CE 3D T1w
	

Coronal T2w SPIR sequence
shows a focal T2w hyperintensity and mild enlargement of the right optic nerve.
Coronal, contrast-enhanced 3D T1w black blood sequence shows a diffuse enhancement of the right optic nerve corresponding to the T2w hyperintensity.

Diagnosis and therapy or follow-up:

The lesions and changes to the optic nerve are possible characteristics of multiple sclerosis (MS) on MR imaging. The MR criteria for spatial and temporal dissemination are met. A MRI of the spine did not show any additional lesion characteristic of MS. The day after the MRI examination, i.e. the second day after hospital admission, the results of the CSF test were already showing the presence of IgG and IgM oligoclonal bands as a laboratory indicator of CNS inflammation consistent with MS. Meanwhile on the same day, the patient reported that she no longer had pain when she moved her eyes. Other clinical symptoms, which would have been consistent with the intracranial MS-typical lesions, were not found in a renewed neurological examination.

A repeated ophthalmological examination on day 4 after hospital admission showed a significant improvement in visual acuity to 0.8 of the right eye with the same good vision of the left eye (VA 1.0) and the papilloedema had almost completely resolved.

The treatment with i.v. methylprednisolone was switched to oral glucocorticoids during the hospital stay. The patient was subsequently discharged home. Regular clinical and imaging follow-ups in an outpatient clinic for chronic inflammatory CNS diseases are scheduled.

Product Indications and Clinical Use – Pixxoscan™ (Gadobutrol injection)

Indications

Pixxoscan (gadobutrol injection) is a medicinal product for diagnostic use only. Pixxoscan (gadobutrol injection) is indicated in adults and children of all ages including term newborns for:

Contrast enhancement during cranial and spinal MRI investigations and for contrast-enhanced magnetic resonance angiography (CE-MRA).

- Contrast enhanced MRI of the breast to assess the presence and extent of malignant breast disease, and MRI of the kidney.
- Pixxoscan is particularly suited for cases where the exclusion or demonstration of additional pathology may influence the choice of therapy or patient management, for detection of very small lesions and for visualization of tumors that do not readily take up contrast media.
- Pixxoscan is also suited for perfusion studies for the diagnosis of stroke, detection of focal cerebral ischemia and tumor perfusion.

Contraindications

Gadobutrol injection should not be administered to patients who have experienced a life-threatening reaction to gadobutrol injection previously.

SERIOUS WARNINGS AND PRECAUTIONS BOX

Serious Warnings and Precautions
Nephrogenic Systemic Fibrosis (NSF)

Gadolinium-based contrast agents (GBCAs) increase the risk for NSF in patients with:

- chronic severe renal insufficiency (glomerular filtration rate <30 mL / min / 1.73m2), or
- acute renal failure / acute kidney injury

In these patients, avoid use of GBCAs unless the diagnostic information is essential and not available with noncontrast-enhanced magnetic resonance imaging (MRI). NSF may result in fatal or debilitating systemic fibrosis affecting the skin, muscle, and internal organs. Screen all patients for renal dysfunction by obtaining a history and / or laboratory tests. When administering a GBCA, do not exceed the recommended dose and allow a sufficient period of time for elimination of the agent from the body prior to any readministration.

- Pixxoscan is intended for intravenous administration only and may cause tissue irritation and pain if administered extravascularly.
- Pronounced states of excitement, anxiety and pain may increase the risk of adverse reactions or intensify contrast medium-related reactions.
- Gadolinium has been detected in brain tissue after multiple exposures to GBCAs, particularly in the dentate nucleus and globus pallidus. In order to minimize potential risks associated with gadolinium accumulation in the brain, it is recommended to use the lowest effective dose and perform a careful benefit risk assessment before administering repeated doses.
- Extravasation into tissues during Pixxoscan administration may result in moderate irritation
- Gadobutrol injection can be associated with anaphylactoid / hypersensitivity or other idiosyncratic reactions, characterized by cardiovascular, respiratory or cutaneous manifestations, and ranging to severe reactions including shock.
- Careful evaluation of the risk-benefit ratio in patients with a history of previous reaction to contrast media, allergic disorders, or bronchial asthma should be made.
- Precautionary measures should be taken with patients predisposed to seizure, eg, close monitoring and availability of injectable anticonvulsants.
- In patients with severely impaired renal function, the benefits of gadobutrol must be weighed carefully against the risks, since elimination will be delayed in such patients.
- Pixxoscan can be removed from the body by hemodialysis. For patients already receiving hemodialysis at the time of Pixxoscan administration, prompt initiation of hemodialysis following the administration of Pixxoscan should be considered, in order to enhance the contrast agent's elimination.
- The safe use of gadobutrol injection during pregnancy has not been established. Pixxoscan should be used during pregnancy only if the benefit justifies the potential risk to the fetus.
- Transfer of gadobutrol into the milk of lactating mothers has not been investigated in humans.
- The cautious utilization of the lowest possible dose of Pixxoscan (0.1 mL / kg body weight) is recommended in the pediatric population under 2 years of age; the recommended dose should not be exceeded and a sufficient period of time for elimination of the agent from the body (at least 7 days) should be allowed prior to re-administration.
- No special precautions are required in elderly patients unless renal function is impaired

Prior to administration, please read the Product Monograph for Pixxoscan and the Important Safety Information About Gadobutrol Based Agents, which is available by calling Customer Service 1 800 387 7146 or through an email request to canadainfo@gehealthcare.com.

Reporting Side Effects

To report SUSPECTED ADVERSE REACTIONS, contact GE HealthCare at 1 800 654 0118 (option 2, then option 1), or email canadainfo@gehealthcare.com to request an adverse events form, or fax to 905 847 5849 to request an adverse events form.

Adverse reactions can also be reported to Health Canada as follows:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health- canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or

  Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Abbreviations:
CE: contrast-enhanced
CNS: central nervous system
CSF: cerebrospinal fluid
FLAIR: FLuid-Attenuated Inversion Recovery
GE: gradient echo
IgG: immunoglobulin G
IgM: immunoglobulin M
i.v.: intravenous
MR: magnetic resonance
MRA: MR angiography
MRI: magnetic resonance imaging
SPIR: Spectral Presaturation with Inversion Recovery

GE Healthcare Canada, 1919 Minnesota Ct,
Mississauga, ON L5N 3C9
www.gehealthcare.ca

04-2025 JB01413CA