Gadobutrol (Gadovist®) versus gadofosveset-trisodium (Vasovist®) in MR venography of the peripheral venous vasculature in deep vein thrombosis: is their a need for blood pool contrast agents?

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Primary objectives:1. To determine image quality and diagnostic accuracy of CE-MRV using a new, optimized high resolution 3D T1 weighted volume interpolated gradient echo sequence with fat suppression (THRIVE) with both a blood pool and a...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Embolism and thrombosis
Study type	Observational invasive

Summary

ID

NL-OMON36357

Source
ToetsingOnline

Brief title
MR Venography in deep vein thrombosis

Condition

- Embolism and thrombosis

Synonym
Deep vein thrombosis

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Deep vein thrombosis, Gadovist, MR venography, Vasovist

Outcome measures

Primary outcome

Image quality of our current method using vasovist will be compared with image quality of the new scan sequence, both with Vasovist and Gadovist as contrast agents. Image quality will assessed both subjectively and objectively. For subjective assessment of image quality a 8-point scale is used to determine clinical suitability and influence of image artifacts. Objective assessment of image quality is performed by measuring the signal-to-noise ratio (SNR) and contrast-to-noise ratio (CNR).

Secondary outcome

Images quality of DSA images will be compared with MRV data using the same method.

Study description

Background summary

Compression ultrasound and Doppler are currently the most widely applied imaging modalities to confirm the diagnosis of deep vein thrombosis (6). These techniques, however, suffer from substantial unexplained heterogeneity, large interobserver variability and the outcome should be interpreted with caution (7). In obese or edematous patients the feasibility of ultrasound based imaging

techniques is poor (6). Besides, using ultrasound it is difficult to determine the extensiveness of deep vein thrombosis. MRI, on the other hand, is a widely available alternative for ultrasound in imaging of the peripheral venous vasculature that does not suffer from these drawbacks (8-12). Moreover, MR venography (MRV) provides accurate, high resolution and easy to interpret morphologic images, that may help simplify treatment planning in patients with deep vein thrombosis, both for the interventional radiologist and the vascular surgeon. Finally, MR venography can help in differentiating deep vein thrombosis from diseases with comparable symptoms, for example iliac vein compression syndrome, also termed May-Thurner syndrome (13).
Different MRV imaging techniques have been described over the years, both contrast-enhanced and non-contrast enhanced. Nevertheless, as of today, literature on MR venography is scarse and based upon current results both contrast-enhanced and non-contrast enhanced MR venography perform equally as far as diagnostic accuracy is concerned (8-12). Contrast-enhanced MRV (CE-MRV) techniques, however, generally have the advantage of faster acquisition times as compared to non-contrast enhanced techniques and, because the acquisitions are 3D, they provide high quality 3D and multiplanar reconstructions.
Currently, in our clinical setting we use for MR venography a contrast-enhanced MRV technique with a blood pool contrast agent (gadofosveset; Vasovist®). In contrast to conventional, small-sized extra-cellular contrast agents, which extravasate into interstitial space quickly and have a short imaging window (the maximum time during which sufficient contrast agent is available in the vessels for MR angiography)(14, 15), this recently introduced blood pool contrast agent is largely prevented from leaking into the interstitial space by a strong, reversible albumin bond. Blood pool agents have large benefits over conventional small-sized extracellular agents in contrast-enhanced venography, because of the prolonged imaging window, which increase the available amount of time to acquire the images, and the relatively large R1 (16), allowing data acquisition at a very high resolution and with very high accuracy.
Unfortunately, however, since last year Vasovist suffers from poor availability in Europe as the production of the contrast agent in Europe has been ceased for strategic reasons and we are currently using the last batch of contrast agent available. In the USA, on the other hand, Gadofosveset has been introduced to the market (Ablavar®, Lantheus Medical Imaging). For the moment, however, it is unclear whether and/or when this contrast agent can be delivered to Europa. Besides, blood pool contrast agents are relatively expensive (costs are 4-5 times higher in comparison with conventional contrast agents, which in the current context is a strong argument). Because of this, we developed a new contrast-enhanced scan sequence, which allow us to acquire high resolution images with good image quality but without the need for blood pool contrast agents. For this new method Gadobutrol (Gadovist®), a conventional, small-sized extracellular contrast agent is used as contrast agent. Gadovist is currently widely used as primary contrast agent for all contrast-enhanced MR examinations apart from angiography at our department. Besides price and availability, there are no important differences between both contrast agents as far as the risk profile and adverse effects of both agents are concerned.

In this study we will use both Vasovist and Gadovist with our new developed scan sequence and compare these results with our current MRV technique using Vasovist in order to prove the value of our new developed scan sequence above our current MRV technique. We hypothesize that our new developed scan sequence will provide both with Vasovist and Gadovist an image quality and diagnostic accuracy comparable, but perhaps even better, than our current MRV technique, which uses Vasovist as contrast agent. Besides we hypothesize that there will be no significant difference in image quality and diagnostic accuracy with our new developed scan between both Vasovist and Gadovist, and therefore with our new scan sequence blood pool contrast agents may be replaced by conventional, small-sized extracellular contrast agents.

Study objective

Primary objectives:
1. To determine image quality and diagnostic accuracy of CE-MRV using a new, optimized high resolution 3D T1 weighted volume interpolated gradient echo sequence with fat suppression (THRIVE) with both a blood pool and a conventional, small-sized extracelluar contrast agent as compared to our current MRV technique (a high resolution contrast-enhanced FFE sequence, serving as the gold standard in this study)
2. To determine differences in image quality and diagnostic accuracy between both contrast agents using the new developed THRIVE sequence.
3. To determine whether Gadovist® is a suitable replacement for Vasovist® in MR venography at our department.
Secondary objective:
1. For those patients who will receive a conventional invasive digital subtraction angiography (DSA) during invasive treatment, DSA data will be compared with the acquired MRV data for assessment of the diagnostic accuracy of MRV.

Study design

Consecutive patients with proven DVT will be asked to participate in this study when being referred to our department of Radiology for a clinical CE-MRV. Patients will be contacted and offered the opportunity to participate in the study, either by their vascular surgeon or the participating radiologists. Patients willing to participate in our study will undergo a CE-MRV examination of the abdomen, the pelvic region, and the upper and lower legs twice, within a period of one week. The first exam comprises a clinical routine CE-MRV (high resolution FFE sequence with Vasovist as contrast agent). This exam will be expended with the new THRIVE sequence, resulting in anincrease in acquisition time of approximately 15 minutes (depending on the dimensions of the patient) as compared to a normal CE-MRV, making the entire exam last for approximately 45 minutes). High resolution images can be obtained untill approximately 1 hour after contrast admission with the use of Vasovist (see product information

Vasovist).
The second examination will comprise the THRIVE sequene only, in combination with Gadovist as contrast agent. Given the fast extravasation of Gadovist into the interstitial space, it is not possible to apply Gadovist for both the THRIVE and FFE sequence during a single exam.
Data from the THRIVE sequences will be used for research purposes only and patients will not benefit from participating in our study, nor will the results of the study interfere with the course of treatment of the included patients.
If patients are scheduled for DSA, DSA data will be compared with CV-MRV data.
Costs associated with transport to the MUMC (and vice versa) and parking at the MUMC for additional imaging will be restituted according to standard guidelines (0,19 ¤ / km, this includes parking).

Study burden and risks

Patient will undergo one extra MRV exam, while their clinical exam will take aprox. 15 minutes longer. Data from the new scan sequences will be used for research purpose only and patients will not benefit from participating in our study, nor will the results of the study interfere with the course of treatment of the included patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Age between 18-65 years
* Objectively documented DVT
* Patient scheduled for CE-MRV
* Patient able to undergo CE-MRV twice within one week
* Patient is not scheduled to receive invasive treatment between both examinations

Exclusion criteria

* Hemodynamic instability
* Known allergy for gadolinium based MR contrast agents
* Contra-indications for MRI
* eGFR < 30 ml/min
* Claustrophobia
* Pregnancy

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	01-11-2011
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	30-06-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL33412.068.10