Patisiran: Management of Extravasation

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RELEVANT CLINICAL TRIAL INFORMATION

During clinical trials, sites were provided with an extravasation prevention guideline (**Table 1**).[1] This is a guideline used in the specific setting of clinical trials and is not given as medical advice. **Therefore, healthcare professionals should use their clinical judgment and practice according to local standard practice for non-vesicants, as recommended in the Prescribing Information.**

Table 1. Extravasation Prevention Guideline.[1]

Extravasation Prevention	Administering IV study drug can result in signs and symptoms of inflammation such as redness, burning sensation, pain, and swelling if there is local extravasation into surrounding tissue at the injection site. Good IV placement is therefore important to prevent extravasation. The following procedures are provided to minimize the risk of extravasation and to ensure appropriate early management should extravasation occur.
IV Infusion Considerations for Study Drug Administration and Extravasation Prevention	Via a peripheral line using an IV cannulae/catheter between 18-22 G: • Select a large vein away from joints or tendons, if possible, e.g., in forearm. (Warming with water may help to dilate veins). Hand veins may be used and may be easier to observe in some patients; however, caution should be taken to prevent extravasation. • Do not use a pre-existing IV of questionable placement, function, or unknown size. • Make a clean venipuncture. Leave the needle entry site visible so that it can be watched during infusion. • Have IV flowing freely at all times with normal saline. Ensure good IV flow prior to any study drug administration. If flow is questionable, do not use for drug administration. Attempt an additional IV placement. • Ensure infusion pump is set at approximately 1 mL/minute for the first 15 minutes followed by approximately 3 mL/minute for the remainder of the infusion and that the drug infusion tubing is connected to the 3-way stopcock. Initiate study drug and watch the infusion site to ensure good flow. Check the infusion site every 2-3 minutes for any evidence of extravasation (swelling or erythema). If there is increased pain during the infusion, check for any evidence of extravasation. • Flush with normal saline. • Elevate limb and maintain gentle pressure over the venipuncture site for five minutes after needle withdrawn.

	Via a central venous catheter: • Prior to administration of study drug, blood should first be aspirated to ensure location in the vein. • A bolus of normal saline (approximately 25 mL) should then be infused to ensure free flow without local discomfort or swelling. Study drug can then be administered. • Following infusion of the study drug, the device should be flushed with at least 25 mL normal saline.
Guide for a Potential Extravasation Event	• Interrupt the study drug infusion. • Consider aspirating the extravasated drug by connecting a clean syringe to the IV access and drawing back on the plunger. • Consider removing the IV line and permitting extravasant to drain from puncture point of IV. Do not place further IVs or venipunctures in the affected limb. Follow these event management recommendations: 1. Firmly apply a cold pack to the extravasated area for 30 minutes every 4 hours for first 24 hours. 2. If an initial inflammatory reaction is observed, when the inflammatory reaction has subsided, a warm compress may be used to aid in dispersal of any residual fluid. 3. Consider application of topical hydrocortisone cream 1% every 6 hours for up to 7 days or as long as any erythema continues. 4. Elevate limb and administer pain relief if needed. 5. Arrange follow up assessments by the site. 6. Sites may resume infusion using a fresh IV in the opposite upper extremity if no definitive extravasation or it was of minimal severity.

Abbreviations: G = gauge; IV = intravenous; mL = milliliter.

ONPATTRO PRESCRIBING INFORMATION – RELEVANT CONTENT

The DOSAGE AND ADMINISTRATION section provides the following information[2]:

Monitor the infusion site for possible infiltration during drug administration. Suspected extravasation should be managed according to local standard practice for non-vesicants.

The ADVERSE REACTIONS section provides the following information[2]:

Extravasation was observed in less than 0.5% of infusions in clinical studies, including cases that were reported as serious. Signs and symptoms included phlebitis or thrombophlebitis, infusion or injection site swelling, dermatitis (subcutaneous inflammation), cellulitis, erythema or injection site redness, burning sensation, or injection site pain.

ABBREVIATIONS

G = gauge; IV = intravenous; mL = milliliter

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REFERENCES

1. Alnylam Pharmaceuticals. Data on file. MED-ALL-TTR02-1800580.
2. ONPATTRO (patisiran) Prescribing Information. Cambridge, MA: Alnylam Pharmaceuticals, Inc.