# Patisiran: Observation Period After Infusion

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## SUMMARY


- In the APOLLO, APOLLO-B, Global OLE, and HELIOS-A studies, patients were observed for 1 hour following completion of the patisiran infusion.[1–4]


## INDEX



## ONPATTRO PRESCRIBING INFORMATION – RELEVANT CONTENT

The **DOSAGE AND ADMINISTRATION** section provides the following information[5]:

***Infusion Instructions***

*Observe the patient during the infusion and, if clinically indicated, following the infusion.*

## CLINICAL DATA

### APOLLO Study

APOLLO was a multicenter, international, randomized (2:1), double-blind, placebo-controlled, phase 3 study designed to assess the efficacy and safety of IV patisiran 0.3 mg/kg every 3 weeks (n=148) versus placebo (n=77) in patients with hATTR-PN. The primary endpoint was the change from baseline in the mNIS+7 at 18 months.[6]

### APOLLO-B Study

APOLLO-B was a multicenter, randomized (1:1), double-blind, placebo-controlled, phase 3 study designed to evaluate the efficacy and safety of IV patisiran 0.3 mg/kg every 3 weeks (n=181) versus placebo (n=179) in patients with ATTR-CM, including both hATTR and wtATTR. The primary endpoint was the change from baseline in the 6-MWT at 12 months. After the 12-month double-blind treatment period, all patients received patisiran in an open-label extension period.[7]

### Global Open-Label Extension Study

The Global OLE study (N=211) was a multicenter, international study designed to evaluate the long-term safety and efficacy of IV patisiran in patients with hATTR-PN. Patients with hATTR-PN who completed the patisiran Phase 2 OLE study or phase 3 APOLLO study and met eligibility criteria were able to start or continue IV patisiran 0.3 mg/kg every 3 weeks for up to 5 years. The study enrolled 25 patients from the patisiran Phase 2 OLE study (Phase 2 OLE-patisiran group), 137 patients from the APOLLO-patisiran arm (APOLLO-patisiran group), and 49 patients from the APOLLO-placebo arm (APOLLO-placebo group).[8]

### HELIOS-A Study

HELIOS-A was a phase 3, global, randomized, open-label study designed to evaluate the efficacy and safety of vutrisiran in patients with hATTR-PN. Patients were randomized (3:1) to receive either vutrisiran 25 mg every 3 months by subcutaneous injection (n=122) or patisiran 0.3 mg/kg every 3 weeks by IV infusion (as a reference group, n=42) for 18 months. This study used the placebo arm of the APOLLO study (NCT01960348) as an external control arm (n=77) for the primary endpoint and most other efficacy endpoints. The primary endpoint was the change from baseline in mNIS+7 at 9 months.[9]

### Observation Period After Infusion

In the APOLLO, APOLLO-B, Global OLE, and HELIOS-A studies, the patient's infusion site was assessed for signs of any localized reaction during the infusion and for 30 minutes after the end of the patisiran infusion. The patient was observed for 1 hour following completion of the patisiran infusion.[1–4]

## ABBREVIATIONS

6-MWT = 6-minute walk test; ATTR-CM = transthyretin amyloidosis with cardiomyopathy; hATTR = hereditary transthyretin amyloidosis; hATTR-PN = hereditary transthyretin amyloidosis with polyneuropathy; wtATTR = wild-type transthyretin amyloidosis; IV = intravenous; mNIS+7 = modified Neuropathy Impairment Score +7; OLE = open-label extension.

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