



Product	Ambelvist™, (Gadoquatrane, BAY1747846)
Swissmedic approval date:	August 28, 2026
Swissmedic approval ID	70440, 70441, 70405

Bayer study ID	Study title	Websynopsis direct link
20241	Multicenter, single-blind, adaptive dose finding study of single intravenous injections of BAY 1747846 with corresponding blinded read in adult participants with known or highly suspected CNS lesions referred for contrast-enhanced MRI of the CNS	https://s3.amazonaws.com/ctr-bsp-7261/20241/f3e3cef7-3dc3-45a7-ab76-a232ff195c10/6ebe0028-ee66-4ab6-a585-4500035ba9e0/20241_Study_Synopsis_CTP-v4.pdf
21181	A multicenter, randomized, prospective double-blind, cross-over Phase 3 study to evaluate the efficacy and safety of 0.04 mmol Gd/kg body weight of gadoquatrane for MRI in adults with known or suspected pathology of the central nervous system (CNS), compared to 0.1 mmol Gd/kg approved macrocyclic gadolinium-based contrast agents (GBCAs)	https://s3.amazonaws.com/ctr-bsp-7261/21181/b468fb03-7997-49aebc12-f943897c406f/240f2b76-e2b7-421b-a61e-baa9430115ff/21181_Study_Synopsis_CTP_09Dec2025-v2.pdf
21196	A multicenter, prospective, open-label study to evaluate the pharmacokinetics and safety of gadoquatrane in pediatric participants (from birth to <18 years) undergoing contrast-enhanced magnetic resonance imaging (CE-MRI)	https://s3.amazonaws.com/ctr-bsp-7261/21196/ea1b4948-30d7-41c6-8681-41491c0a2499/ebec995f-df66-469f-a504-21385b7ade33/21196_Websynopsis_06MARCH2025-v2.pdf
21197	A multicenter, randomized, prospective double-blind, cross over Phase 3 study to evaluate the efficacy and safety of 0.04 mmol Gd/kg body weight of gadoquatrane for MRI in adults with known or suspected pathology of any body region (except CNS), compared to 0.1 mmol Gd/kg approved macrocyclic gadolinium-based contrast agents (GBCAs)	https://s3.amazonaws.com/ctr-bsp-7261/21197/3cdd6472-f27e-48fa-8b33-de4a14593f28/3320d8b7-c06d-4f7d-8515-edf6c6c63b4c/21197_Study_Synopsis_CTP_21Nov2025-v2.pdf