Clinical trial information

Registration Item	Details of registration Item	Contents
Title of the study	Title of the study	A Phase 2, Multi-center, Randomized, Double-blind, Placebo-controlled Study of T-817MA in Post-stroke Patients Undergoing Rehabilitation for Upper Limb Hemiplegia
	Primary sponsor	FUJIFILM Toyama Chemical Co. Ltd
	Study Type	interventional (drug)
	Summary	To evaluate the efficacy and dose-response relationship of T-817MA by oral administration of T-817MA or placebo in patients with upper limb hemiplegia after stroke undergoing rehabilitation. The safety and pharmacokinetics of T-817MA will also be evaluated.
Details of study	Interventional drug name	Edonerpic (T-817MA)
	Target illness	Patients with upper limb hemiplegia after cerebral infarction or cerebral hemorrhage (other than subarachnoid hemorrhage)
	Classification name (code) of the investigational drug	119 Miscellaneous
	Administration route	Oral Multiple Dose
	Control drug name(code/td)	-
	Classification name (code) of the investigational drug	-
	Administration route	-
	Objectives of the study	Treatment
	Study phase	Phase II
	Study design	Multi-center, Randomized, Double-blind, Placebo- contr olled Study

	Criteria	Inclusion 1.Age:20 years old to less than 85 years old 2.Sex: No restriction 3. Japanese people resident in Japan 4. Patients diagnosed with initial stroke from MRI or CT 5. Taking the onset date of the stroke to be Day 1 of onset, patients who are able to start administration of the study drug within the period of Days 22 to 56 of onset 6. Patients with serve to moderate upper limb motor functional impairment 7. Patients who can undergo hospitalization and rehabilitation during the study drug administration period Exclusion 1. Patients who showed marked improvement with rehabilitation alone or patients with poor prognosis who show no effect from rehabilitation . in the screening period 2. Patients who cannot perform joint movement due to synkinesis of upper limb or finger mass flexion 3. Patients with concurrent psychiatric disease such as dementia, depression or schizophrenia 4. Patients with diseases or symptoms that make it difficult to perform rehabilitation of the upper limb or evaluate efficacy 5. Patients with concurrent conditions for which movement of the upper limbs is contraindicated (patients with severe heart disease, uncontrolled hypertension, recent pulmonary embolism or severe orthopedic disease) 6. Patients with historical or concurrent epilepsy 7. Patients who developed convulsion after the onset of stroke 8. Others
	Outcome	efficacy and safety
	Study status	
	Duration of the study	-
	Region	Japan
Contact information	Organization	FUJIFILM Toyama Chemical Co. Ltd
	Division	Development Coordination Department
	Contact	Form for Inquiry: https://www.fujifilm.co.jp/form/fftc/ja/general/input.php?id=FFTCClinicalEn