Clinical trial information

Registration Item	Details of registration Item	Contents
Title of the study	Title of the study	A Phase III, multi-center, randomized, double-blind, non-inferiority study of Solithromycin versus Levofloxacin in patients with community-acquired pneumonia
	Primary sponsor	Toyama Chemical Co., Ltd.
	Study Type	interventional (drug)
	Summary	To demonstrate non-inferiority of Solithromycin against Levofloxacin in patients with community-acquired pneumonia
Details of study	Interventional drug name	T-4288 (Solithromycin)
	Target illness	Community-acquired pneumonia
	Classification name (code) of the investigational drug	614 Acting mainly on gram-negative bacteria
	Administration route	Oral Multiple Dose
	Control drug name(code/td)	LVFX (Levofloxacin)
	Classification name (code) of the investigational drug	624 Synthetic antibacterials
	Administration route	Oral Multiple Dose
	Objectives of the study	To demonstrate non-inferiority of Solithromycin against Levofloxacin in patients with community-acquired pneumonia
	Study phase	Phase III
	Study design	Randomized, Multi-center, Double-Blind study
	Inclusion Criteria	1. Age: 20 years of age and older (at the time of obtaining informed consents) 2. Gender : Both 3. Inpatient/Outpatient status: Either 4. No history of hospitalization or hospitalization in a long-term care facility within 2 weeks before the onset of pneumonia 5. Confirmed clear infiltrative shadow by chest X-ray or CT within 48 hours prior to the first administration of the study drug 6. Signed the informed consent form by patients or patients' legal representatives 7. Others
	Outcome	Efficacy and safety profile
	Study status	Completed
	Duration of the study	-
	Region	Japan
Contact information	Organization	Toyama Chemical Co., Ltd.
	Division	Data Science and Administration Department
	Contact	Form for Inquiry https://www.toyama-chemical.co.jp/en/form/general/input.php?id=TCClinicalEn