Clinical trial information

Registration Item	Details of registration Item	Contents
Title of the study	Title of the study	A Phase II, multi-center, randomized, double-blind study of T-4288 in patients with community-acquired pneumonia
	Primary sponsor	Toyama Chemical Co., Ltd.
	Study Type	interventional (treatment)
	Summary	To evaluate the efficacy, pharmacokinetic and safety of T-4288 in patients with mild to moderate 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-positive bacteria and mycoplasma)
	Administration route	Oral Multiple Dose
	Control drug name(code/td)	Levofloxacin
	Classification name (code) of the investigational drug	624 (Synthetic antibacterials)
	Administration route	Oral Multiple Dose
	Objectives of the study	To evaluate the efficacy, safety and pharmacokinetic profile
	Study phase	Phase II
	Study design	Multi-center, Randomized, Double-Blind, Active-controlled study
	Inclusion Criteria	1. Age: 20 years of age and older 2. Gender : Both 3. Confirmed clear infiltrative shadow by chest X-ray or CT within 48 hours prior to the first administration of the study drug 4. Confirmed at least one of the following changes in laboratory values; -WBC increased (WBC > 10000 /mm^3) -Stab cell > 15% -WBC decreased (WBC < 4500 /mm^3) 5. Confirmed at least one of the following clinical symptoms and/or findings: -Cough -Abnormal findings on auscultation and/or percussion - Dyspnea or tachypnea -Hypoxemia 6. Others
	Outcome	efficacy, safety and pharmacokinetic profile
	Study status	Completed
	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