

Clinical trial information

Registration Item	Details of registration Item	Contents
Title of the study	Title of the study	A Phase 3, Multicenter, Randomized, Double-Blind Noninferiority Study of Oral Solithromycin Compared to Oral Azithromycin in the Treatment of Patients with Community-Acquired Pneumonia
	Primary sponsor	FUJIFILM Toyama Chemical Co., Ltd.
	Study Type	interventional study (drug)
	Summary	To demonstrate noninferiority of solithromycin against azithromycin in patients with community-acquired pneumonia
Details of study	Interventional drug name	Solithromycin
	Target illness	Community-acquired pneumonia
	Classification name (code) of the investigational drug	614
	Administration route	Oral Multiple Dose
	Control drug name(code/td)	Azithromycin
	Classification name (code) of the investigational drug	614
	Administration route	Oral Multiple Dose
	Objectives of the study	treatment
	Study phase	Phase III
	Study design	Multicenter, Stratified Randomized, Double-Blind Study
	Criteria	<p>inclusion criteria</p> <ol style="list-style-type: none"> 1. Age: 20 years or older (at the time of obtaining informed consent) 2. Sex : Irrespective 3. Outpatient/hospitalization: Irrespective 4. Patients with no history of hospitalization within 2 weeks before the development of pneumonia, or no history of hospitalization in a long-term care institution 5. Patients with newly developed infiltrative shadow on either chest X-ray imaging or computed tomography (CT) imaging taken within 48 hours before the start of study drug administration 6. Patients from whom written informed consent can be obtained from the patients themselves 7. Others <p>exclusion criteria</p> <ol style="list-style-type: none"> 1. Patients with symptoms which are showing improvement by having received systemic oral antibacterial drugs 2. Patients with a history of allergy to macrolides or ketolides 3. Others

	Outcome	Efficacy and Safety
	Study status	Recruiting
	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/ffc/ja/general/input.php?id=FFTCClinicalEn