Clinical trial information

Registration Item	Details of registration Item	Contents
Title of the study	Title of the study	Phase III study of Garenoxacin in the treatment of community-acquired pneumonia - A randomized, multi-center, double-blind, double-dummy and comparative study -
	Primary sponsor	Toyama Chemical Co., Ltd.
	Study Type	interventional (treatment)
	Summary	This is a randomized, multi-center, double-blind, double-dummy and comparative study to evaluate the clinical efficacy, bacteriological responses and safety of garenoxacin, dosed at 400 mg once daily for 7-10 days, in the patients with community-acquired pneumonia .
Details of study	Interventional drug name	Garenoxacin 200 mg tablet
	Target illness	Patients with community-acquired pneumonia
	Classification name (code) of the investigational drug	624 (synthetic antibacterials)
	Administration route	Oral administration
	Control drug name(code/td)	Levofloxacin 500 mg tablet
	Classification name (code) of the investigational drug	624 (synthetic antibacterials)
	Administration route	Oral administration
	Objectives of the study	Medical treatment
	Study phase	Phase 3
	Study design	
	Inclusion Criteria	1) History of hypersensitive reaction to any quinolone antibacterial agents. 2) History of twitch and/or epilepsia or taking antiepileptic agents. 3) Pregnant females, females wishing to become pregnant or being possibly pregnant, and lactating females. 4) Patients with severe infection requiring tretment with injectable antibacterial agents or mechanical ventilator. 5) Others.
	Outcome	Clinical efficacy, bacteriological responses and safety
	Study status	Completed
	Duration of the study	From 1st Dec. 2011 to 30th Nov. 2012
	Region	The People's Republic of China
Contact information	Organization	Toyama Chemical Co., Ltd.
	Division	Clinical Planning Department
	Contact	Form for Inquiry https://www.toyama-chemical.co.jp/en/form/general/input.php?id=TCClinicalEn