Clinical trial information

Registration Item	Details of registration Item	Contents
Title of the study	Title of the study	A Phase III, multi-center, open-label study of Solithromycin in patients with otorhinolaryngological infection
	Primary sponsor	Toyama Chemical Co., Ltd.
	Study Type	interventional (drug)
	Summary	To evaluate the efficacy and safety of Solithromycin in patients with otorhinolaryngological infection (acute otitis media, laryngopharyngitis and tonsillitis)
Details of study	Interventional drug name	T-4288 (Solithromycin)
	Target illness	Acute otitis media, laryngopharyngitis and tonsillitis
	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)	-
	Classification name (code) of the investigational drug	-
	Administration route	-
	Objectives of the study	To evaluate the clinical efficacy and safety of Solithromycin in patients with otorhinolaryngological infection (acute otitis media, laryngopharyngitis and tonsillitis)
	Study phase	Phase III
	Study design	Open-label, Multi-center 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: Outpatient 4) Signed the informed consent form by patients 5) Otorhinolaryngological infection with clear infection symptoms
	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