

Clinical trial information

Registration Item	Details of registration Item	Contents
Title of the study	Title of the study	An otorhinolaryngological tissue penetration study of T-4288 in patients scheduled for surgery
	Primary sponsor	Toyama Chemical Co., Ltd.
	Study Type	interventional (treatment)
	Summary	To evaluate the penetration of T-4288 in sinus mucosa, middle ear mucosa or palatine tonsil tissue
Details of study	Interventional drug name	T-4288 (Solithromycin)
	Target illness	chronic sinusitis, chronic otitis media, chronic tonsillitis or palatine tonsil hypertrophy
	Classification name (code) of the investigational drug	614 (Acting mainly on gram-positive bacteria and mycoplasma)
	Administration route	Oral Single Dose
	Control drug name(code/td)	-
	Classification name (code) of the investigational drug	-
	Administration route	-
	Objectives of the study	To evaluate the safety and pharmacokinetic profile
	Study phase	Phase II
	Study design	Multi-center, Open-labeled study
	Inclusion Criteria	1. Age: 20 years of age and older 2. Gender : Both 3. Other
	Outcome	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