

## Clinical trial information

Registration Item	Details of registration Item	Contents
Title of the study	Title of the study	A Phase III, multi-center, randomized, double-blind, non-inferiority study of Solithromycin versus Cefcapene pivoxil hydrochloride hydrate in patients with sinusitis
	Primary sponsor	Toyama Chemical Co., Ltd.
	Study Type	interventional (drug)
	Summary	To demonstrate non-inferiority of Solithromycin against Cefcapene pivoxil hydrochloride hydrate in patients with sinusitis
Details of study	Interventional drug name	Solithromycin (T-4288)
	Target illness	Sinusitis
	Classification name (code) of the investigational drug	614 (antibiotic preparations acting mainly on gram-positive bacteria and mycoplasma)
	Administration route	Oral Multiple Dose
	Control drug name(code/td)	Cefcapene pivoxil hydrochloride hydrate
	Classification name (code) of the investigational drug	613 (antibiotic preparations acting mainly on gram-positive gram-negative bacteria)
	Administration route	Oral Multiple Dose
	Objectives of the study	To demonstrate non-inferiority of Solithromycin against Cefcapene pivoxil hydrochloride hydrate in patients with sinusitis
	Study phase	Phase 3
	Study design	Randomized, Multi-center, Double-Blind study
	Inclusion Criteria	<p>Inclusion</p> <ol style="list-style-type: none"> <li>1.Age: 20 years of age and older (at the time of obtaining informed consents)</li> <li>2.Gender : Both</li> <li>3.Inpatient/Outpatient status: Outpatient</li> <li>4.Signed the informed consent form by patients</li> <li>5.Sinusitis with clear infection symptoms</li> </ol> <p>Exclusion</p> <ol style="list-style-type: none"> <li>1.Having improvement of clinical symptoms due to target disease by other systemic antibiotics</li> <li>2.Having a history of allergy to macrolide, penicillin or cephem antibiotics</li> <li>3.Others</li> </ol>
	Outcome	efficacy and safety profile
	Study status	Completed
	Duration of the study	-
Region	Japan	
Contact information	Organization	Toyama Chemical Co., Ltd.
	Division	Clinical Planning Department
	Contact	Form for Inquiry <a href="https://www.toyama-chemical.co.jp/en/form/general/input.php?id=TCClinicalEn">https://www.toyama-chemical.co.jp/en/form/general/input.php?id=TCClinicalEn</a>