

Clinical trial information

Registration Item	Details of registration Item	Contents
Title of the study	Title of the study	Food effect study of T-4288 in healthy adult subjects
	Primary sponsor	Toyama Chemical Co., Ltd.
	Study Type	interventional (treatment)
	Summary	To evaluate the effects of food on the bioavailability of T-4288 in healthy adult subjects
Details of study	Interventional drug name	T-4288 (Solithromycin)
	Target illness	Japanese healthy adult subjects
	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 effects of food on the bioavailability of T-4288 in healthy adult subjects
	Study phase	Phase I
	Study design	Randomized, 2- group, 2-period Crossover study
	Criteria	<p>Inclusion Criteria</p> <ol style="list-style-type: none"> 1. Japanese healthy subjects between 20 and 39 years of age 2. BMI between 18.0 and 30.0 kg/ m² 3. Understand the requirements of the study and voluntarily consent to participate in the study 4. Others <p>Exclusion Criteria</p> <ol style="list-style-type: none"> 1. Have a history or presence of clinically significant cardiovascular, dermatologic, endocrine, gastrointestinal, hematologic, hepatic, immunologic, neurologic, oncologic, psychiatric, pulmonary, or renal disease or any other condition, which, in the opinion of the PI, would jeopardize the safety of the subject or impact the validity of the study results 2. Have a history of allergy to macrolide antibiotics 3. Others
	Outcome	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