

## Clinical trial information

Registration Item	Details of registration Item	Contents
Title of the study	Title of the study	An Open-label, One-sequence Crossover Study of Solithromycin to Evaluate the Effects on the Pharmacokinetics of Metformin Hydrochloride in Healthy Adult Subjects
	Primary sponsor	FUJIFILM Toyama Chemical Co., Ltd.
	Study Type	interventional study (drug)
	Summary	To evaluate the effect of solithromycin on metformin pharmacokinetics in healthy adult subjects
Details of study	Interventional drug name	Solithromycin (T-4288)
	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 Multiple Dose
	Control drug name(code/td)	-
	Classification name (code) of the investigational drug	-
	Administration route	-
	Objectives of the study	Other (Drug-drug interaction)
	Study phase	Phase I
	Study design	Open-label, One-sequence Crossover
	Criteria	<p>Inclusion</p> <ol style="list-style-type: none"> <li>1. Japanese healthy subjects between 20 and 55 years of age</li> <li>2. BMI between 18.0 and 30.0 kg/ m<sup>2</sup></li> <li>3. Understand the requirements of the study and voluntarily consent to participate in the study</li> </ol> <p>Exclusion</p> <ol style="list-style-type: none"> <li>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 Investigator, would jeopardize the safety of the subject or impact the validity of the study results</li> <li>2. Have a history of allergy to macrolide antibiotics or biguanides</li> </ol>
	Outcome	Pharmacokinetics and safety
	Study status	On going
	Duration of the study	-
Region	Japan	
Contact information	Organization	FUJIFILM Toyama Chemical Co., Ltd.
	Division	Development Coordination Department
	Contact	Form for Inquiry: <a href="https://www.fujifilm.co.jp/form/ftc/ja/general/input.php?id=FFTCClinicalEn">https://www.fujifilm.co.jp/form/ftc/ja/general/input.php?id=FFTCClinicalEn</a>