

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"> 1. Japanese healthy subjects between 20 and 55 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 <p>Exclusion</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 Investigator, would jeopardize the safety of the subject or impact the validity of the study results 2. Have a history of allergy to macrolide antibiotics or biguanides |
| | Outcome | Pharmacokinetics and safety |
| | Study status | Completed |
| | Duration of the study | - |
| Region | Japan | |
| Contact information | Organization | FUJIFILM Toyama Chemical Co., Ltd. |
| | Division | Development Coordination Department |
| | Contact | Form for Inquiry: https://www.fujifilm.co.jp/form/ftc/ja/general/input.php?id=FFTCClinicalEn |