Clinical trial information

Registration Item	Details of registration Item	Contents
Title of the study	Title of the study	Phase3 study of T-1220 in the patients with bacterial infectious disease －Open label, multi-center study－
	Primary sponsor	Toyama Chemical Co., Ltd
	Study Type	interventional (treatment)
	Summary	The objective of the study is to evaluate the safety and efficacy of T-1220 when given the increased dosage in patients with severe infectious disease of which T-1220 has the indication. In addition the other objective is to evaluate the pharmacokinetic and pharmacodynamic of safety and efficacy.
Details of study	Interventional drug name	Piperacillin Sodium
	Target illness	Sepsis, Acute bronchitis, Pneumonia, Lung abscess, Pyothorax, Secondary infection of chronic respiratory disease, Cystitis, Pyelonephritis, Cholecystitis, Cholangitis, Bartholinitis, Intrauterine infection, Uterine adnexitis, Parametritis, Purulent meningitis
	Classification name (code) of the investigational drug	613
	Administration route	Intravenous drip
	Control drug name (code/td)	-
	Objectives of the study	Treatment
	Study phase	Phase 3
	Study design	Open label, multi-center study
	Inclusion Criteria	(1) Sex:male or female (2) Age: 20 years and older for adult and 28 days to 16 years old (inclusive) for child (3) Outpatient or inpatient: inpatient (4) Presence of definite symptom/findings of infectious disease (5) Others
	Exclusion Criteria	(1) Medical history of allergy to any β-lactam antibacterial agents. (2) Patient with infectious mononucleosis. (3) Pregnant females, females wishing to become pregnant or being possibly pregnant, and lactating females. (4) Others.
	Outcome	Efficacy and safety
	Study status	Completed
	Duration of the study	
	Region	Japan
	Organization	Toyama Chemical Co., Ltd.
	Division	Clinical Planning Department
Contact information	Form for Inquiry https://www.toyama-chemical.co.jp/en/form/general/input.php?id=TCClinicalEn	