

Clinical trial information

Registration Item	Details of registration Item	Contents
Title of the study	Title of the study	Phase IIb Study of F-1311 in Patients with Prostate Cancer
	Primary sponsor	FUJIFILM RI Pharma Co., Ltd.
	Study Type	interventional (drug)
	Summary	Study to evaluate the efficacy and safety of F-1311 in patients with prostate cancer
Details of study	Interventional drug name	F-1311
	Target illness	Prostate Cancer
	Classification name (code) of the investigational drug	430 (radioactive medicines)
	Administration route	intravenous injection
	Objectives of the study	Diagnostic
	Study phase	Phase II
	Study design	multicenter, open-label
	Target sample size	56
	Criteria	<p>Inclusion Criteria</p> <ul style="list-style-type: none"> - Age : 20 years old or more - Sex : Male - Biopsy confirmed presence of adenocarcinoma of the prostate gland. - Gleason score 6 or 7 - PSA < 10 ng/mL <p>Exclusion Criteria</p> <ul style="list-style-type: none"> - Subjects have received or have been receiving treatment or medication for prostate cancer. - Subjects have sever hepatic or renal dysfunction.
	Outcome	Ability of F-1311 to accumulate in prostate cancer, safety
	Study status	Study Completed
	Duration of the study	2016-4-1 ~ 2017-3-31
Region	Japan	
Contact information	Organization	FUJIFILM RI Pharma Co., Ltd.
	Division	Development Dept.
	Contact	03-5250-2634