

# Acute Safety and Efficacy of the Pivot Bridge System for Functional Tricuspid Regurgitation

NCT07385625

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Status	RECRUITING
Phase	Not Applicable
Sponsor	Tau-MEDICAL Co., Ltd.
Enrollment	20 participants

## Key Eligibility Criteria

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### Inclusion (9)

- Subjects who meet all of the following criteria will be enrolled
- Adults aged 18 years or older at the time of screening
- Subjects who have received appropriate medical treatment (diuretics/medical therapy) for tricuspid regurgitation for at least 1 month prior to participation in this clinical trial
- Subjects who, at the screening visit, are assessed by transthoracic echocardiography (TTE) to have functional tricuspid regurgitation severity of Massive (4+) or greater, as defined by Tricuspid Valve Academic Research Consortium classification, and who have clinical symptoms corresponding to New York Heart Association (NYHA) functional class II or higher
- Subjects who, at the screening visit, are found on TTE or cardiac computed tomography (CT) to have a right ventricle (RV) larger than the left ventricle (LV)

... and 4 more (see full listing online)

### Exclusion (22)

- Subjects who meet any of the following criteria will be excluded
- Subjects in whom thrombus or embolic material is identified on echocardiography or cardiac computed tomography (CT) performed at the screening visit
- Subjects who have uncorrected coagulation disorders as shown by clinical laboratory tests performed at the screening visit
- Subjects who cannot use anticoagulant agents
- Subjects who, prior to participation in this clinical trial, have experienced major bleeding due to the use of anticoagulants (minor bleeding such as controllable epistaxis does not apply) requiring treatment, or who have had severe anemia necessitating hospitalization

... and 17 more (see full listing online)

## Locations (4 total)

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Keimyung University Dongsan Hospital, Daegu, Dalseo-gu, South Korea  
Pusan National University Yangsan Hospital, Yangsan, Gyeongsangnam-do, South Korea  
Yonsei University Health System, Severance Hospital, Seoul, Seodaemun-gu, South Korea  
... and 1 more locations