

INFLATE Study: Investigation of the Safety and Performance of a Novel PTV Balloon in Patients Undergoing TAVI for Severe Aortic Stenosis

NCT06816485

Status	RECRUITING
Phase	Not Applicable
Sponsor	Biosensors Europe SA
Enrollment	93 participants

Key Eligibility Criteria

Inclusion (6)

- Symptomatic severe calcific stenosis of a native aortic valve with an AVA ≥ 1.0 cm² (or AVA index ≥ 0.6 cm²/m²) AND mean aortic pressure gradient ≥ 40 mmHg OR maximal transaortic velocity ≥ 4.0 m/s OR Doppler velocity index ≥ 0.25 on site-reported echocardiography
 - Local multi-disciplinary Heart Team agrees on indication and eligibility for TAVI
 - Age ≥ 18 years
 - Patient has signed the Patient Informed Consent Form
 - Patient is willing and able to comply with requirements of the study
- ... and 1 more (see full listing online)

Exclusion (23)

- Mean aortic annulus diameter as measured by pre-procedural CT or internal diameter of the bioprosthesis is < 16 mm or > 30 mm
 - Echocardiographic evidence of intracardiac thrombus, mass or vegetation (site-reported)
 - Significant disease of the aorta that would preclude safe advancement of the TAVI system
 - Severe ilio-femoral vessel disease that would preclude safe performance of the TAVI procedure
 - Severe tricuspid regurgitation and/or failing right heart (site-reported)
- ... and 18 more (see full listing online)

Locations (7 total)

Hospital de la Santa Creu i Sant Pau, Barcelona, Spain
Hospital Universitari de Bellvitge, Barcelona, Spain
Hospital Universitario Reina Sofia, Córdoba, Spain
... and 4 more locations