Towards a More Standardized Bicuspid Aortic Valve Repair: Rationale and Design of CONTOUR Trial - a Randomized Trial

NCT06869954

Status	RECRUITING
Phase	Not Applicable
Sponsor	University Hospital Augsburg
Enrollment	100 participants

Key Eligibility Criteria

Inclusion (5)

- Presence of fused BAV phenotype with an asymmetric configuration (commissural orientation \< 170 degree) \[14\]
- Severe aortic regurgitation (vena contracta (vc) \> 6mm and/or pressure half-time (PHT) \< 200 ms and/or effective regurgitant orifice area (EROA) \> 30 mm2 and/or regurgitant volume (RV) \> 60 ml/beat and/or left ventricular end-systolic diameter (LVESD) \> 50mm (or indexed LVESD \> 20mm/m2 BSA) and/or regurgitation fraction (RF) in cardiothoracic MRI \> 40%) (at least one parameter is required) \[15\]
- Isolated aortic valve surgery or concomitant procedure (including CABG and/or mitral/tricuspid valve surgery and/or ascending aortic surgery)
- Willingness to participate and written informed consent
- Age at surgery \> 18 years

Exclusion (5)

- Moderate/severe BAV stenosis (pmean \> 20mmHg)
- Moderate/severe BAV cusp calcifications extending beyond the raphe region and/or necessitating patch implantation (deemed irreparable based on preoperative TOE (as by decision of the operating surgeon)
- Concomitant aortic root aneurysm \> 45mm requiring simultaneous aortic root surgery \[16\]
- Acute/subacute BAV endocarditis
- Contraindication to MRI

Locations (4 total)

University Hospital Augsburg, Augsburg, Bavaria, Germany
University Heart and Vascular Center Frankfurt, Frankfurt am Main, Hesse, Germany
Heart Center Leipzig, Leipzig, Saxony, Germany
... and 1 more locations