

Comparative Research of Y-Incision vs. Standard Techniques for Aortic Root EnLargement

NCT07368322

Status	RECRUITING
Phase	Not Applicable
Sponsor	willner nadav MD
Enrollment	90 participants

Key Eligibility Criteria

Inclusion (5)

- Adults aged 18-80 years.
- Patients must have signed and dated an ICF in accordance with regulatory and institutional guidelines before any protocol-related procedures and must be willing and able to comply with scheduled visits.
- Diagnosed with aortic valve disease requiring aortic valve replacement.
- Patients with small aortic annulus relative to body size where conventional AVR result in moderate or severe PPM (defined as cases where the largest prosthesis that can be implanted in the native annulus would provide a predicted iEOA $<0.85 \text{ cm}^2/\text{m}^2$ for BMI <30 , or $<0.70 \text{ cm}^2/\text{m}^2$ for BMI ≥ 30), based on manufacturer specifications and patient BSA).
- Suitable candidates for surgery as determined by the heart team.

Exclusion (9)

- Patients for whom conventional AVR without root enlargement is not expected to result in patient-prosthesis mismatch.
 - Prior cardiac surgery.
 - Severe concomitant valvular disease requiring additional procedures.
 - Active endocarditis.
 - Severe chronic lung disease
- ... and 4 more (see full listing online)

Locations (1 total)

Rambam Health Care Campus, Haifa, Israel