

Treating Severe Mitral Valve Annular or Valvular Calcification Using Shockwave Balloon SMARTWAVE

NCT06952374

Status	RECRUITING
Phase	Not Applicable
Sponsor	Prince of Wales Hospital, Shatin, Hong Kong
Enrollment	10 participants

Key Eligibility Criteria

Inclusion (5)

- Age ≥ 18 and
- Able to give procedure and study consent and
- Severe symptomatic mitral stenosis (MVA $< 1.5\text{cm}^2$ derived by 3D planimetry or continuity equation or pressure half time) and
- Presence of mitral annular calcification or
- CRHD with severe leaflet calcification with Wilkins score ≥ 8

Exclusion (5)

- Baseline $>$ moderate MR
- Intracardiac thrombus as visualized by TEE
- Pregnant patients. Female patients of childbearing potential must have a negative pregnancy test (per site standard test) within 7 days prior to index procedure.
- Active infection with bacteremia
- Current participation in another investigational drug or device study

Locations (1 total)

Prince of Wales Hospital, Shatin, New Territories, Hong Kong