

The Safety and Performance of ShockPulse-10 in Patients with Coronary Artery Calcification

NCT06711822

Status	RECRUITING
Phase	Not Applicable
Sponsor	Keya Medical
Enrollment	205 participants

Key Eligibility Criteria

Inclusion (10)

- Patient is ≥ 18 years of age;
- Patients with significant coronary artery disease (including stable or unstable angina and asymptomatic myocardial ischemia) who are suitable for PCI treatment;
- A single newly developed stenosis of the target vessel, which is the left anterior descending artery, right coronary artery, or circumflex artery (or its branches), with stenosis degree $\geq 70\%$ or $\geq 50\%$ (Visually inspect) and accompanied by evidence of ischemia;
- The target lesion is a primary, in situ coronary artery lesion;
- The reference vessel diameter for the target lesion is 2.0-4.0mm, and the length of the target lesion is ≤ 40 mm (Visually inspect);
- ... and 5 more (see full listing online)

Exclusion (8)

- Left ventricular ejection fraction $< 40\%$
- NYHA class III or IV heart failure
- Patients with single coronary artery supply;
- Patients with evidence of dissection at the site of the lesion on imaging;
- The imaging suggests that the vascular pathway is tortuous, making it difficult for the pre-dilatation device to reach the target location or to be retrieved;
- ... and 3 more (see full listing online)

Locations (1 total)

Beijing Anzhen Hospital, Beijing, Beijing Municipality, China