

Trial to Assess Non-inferiority of an Orbital Atherectomy Only Versus a Calcium-tailored Debulking Approach

NCT07105930

Status	RECRUITING
Phase	Not Applicable
Sponsor	IHF GmbH - Institut für Herzinfarktforschung
Enrollment	310 participants

Key Eligibility Criteria

Inclusion (4)

- Age ≥ 18 Years
- Chronic coronary syndrome with a clinical indication for percutaneous coronary intervention of a severely calcified lesion as defined by coronary computer tomography (CT; Agatston Score of target lesion ≥453 OR Calcium Arc >270°). The determination of calcification in the target lesion is based on native and contrast enhanced CT scans that are conducted as per clinical guidelines. The CT images must not be older than 6 months at the time of patient enrollment.
- Signed informed consent
- The patient is an appropriate candidate for bypass surgery, angioplasty, or atherectomy therapy

Exclusion (15)

- Acute ST-Elevation Acute Coronary Syndrome (STE-ACS) within 48 hours
- Cardiogenic shock
- Chronic total occlusion of the target lesion
- Glomerular filtration rate < 30 ml/min/1.73 m²
- Known presence, at the time of enrollment, of any contraindications listed in the Instructions for Use (IFU) of the investigational device:
... and 10 more (see full listing online)

Locations (1 total)

Universitäres Herz - und Gefäßzentrum, Universitätsklinikum Frankfurt, Frankfurt, Germany