

Drug-Coated Balloon vs. Drug-Eluting Stent for Clinical Outcomes in Patients With Large Coronary Artery Disease

NCT05846893

Status	RECRUITING
Phase	Not Applicable
Sponsor	B. Braun Medical Industries Sdn. Bhd.
Enrollment	1,436 participants

Key Eligibility Criteria

Inclusion (11)

- Patient-related:
 - Patient must be e 18 years of age
 - Patient is able to verbally confirm understanding of the study aim, risks, benefits, and treatment alternatives of receiving DCB or DES and he/she or his/her legally authorized representative provides written informed consent prior to any study-related procedure
 - (i) Clinical evidence of angina, and/or (ii) an abnormal functional study demonstrating myocardial ischemia due to the target lesion(s), or (iii) acute coronary syndrome \[unstable angina or non-ST-elevation myocardial infarction (NSTEMI) or uneventful STEMI (e 48 hours after primary PCI and no sign of thrombus in lesion(s) to treat)\]
 - Patient with lesions suitable for PCI with a DCB (and/or DES) according to the Instructions for Use
- ... and 6 more (see full listing online)

Exclusion (21)

- Patient-related:
 - Intolerance or allergy to Paclitaxel and/or the delivery matrix (main ingredient: Iopromide)
 - Severe allergy to contrast media
 - Recent STEMI (ongoing or < 48 hours after primary PCI and/or has sign of thrombus in lesion(s) to treat)
 - NSTEMI hemodynamically unstable
- ... and 16 more (see full listing online)

Locations (19 total)

Queen Elizabeth II Hospital, Kota Kinabalu, Sabah, Malaysia
Sarawak Heart Center, Kuching, Sarawak, Malaysia
Sultan Idris Shah Serdang Hospital, Kajang, Selangor, Malaysia
... and 16 more locations

<https://clinicaltrials.gov/study/NCT05846893>

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