

# Drug-Coated Balloon Versus Drug-Eluting Stent for Treatment of De-Novo Coronary Lesions in Patients With High Bleeding Risk-2

NCT06742931

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Status	RECRUITING
Phase	Not Applicable
Sponsor	Samsung Medical Center
Enrollment	1,200 participants

## Key Eligibility Criteria

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### Inclusion (6)

- Subject must be at least 19 years of age
- Subject who is able to understand risks, benefits and treatment alternatives and sign informed consent voluntarily.
- Patients with chronic coronary syndrome and at least one de novo lesion of reference vessel size  $\geq 2.25$  mm, treated with DCB angioplasty
- Patients with high bleeding risk: one or more of the criteria listed A. Age  $\geq 75$  years old B. Baseline Hemoglobin  $< 11$  g/dl (or anemia requiring transfusion during the 4 weeks prior to randomization) C. Any prior intra-cerebral bleed D. Hospital admission for bleeding during the prior 12 months E. Non skin cancer diagnosed or treated  $< 3$  years F. Planned daily NSAID (other than aspirin) or steroids for  $> 30$  days after PCI G. Planned surgery that would require interruption of DAPT (within next 12 months) H. Renal failure defined as calculated creatinine clearance  $< 40$  ml/min or on dialysis I. Hematological disorders (platelet count  $< 100,000/\text{mm}^3$  or any coagulation disorder) J. Severe chronic liver disease defined as patients who have developed any of the following: variceal hemorrhage, ascites, hepatic encephalopathy or jaundice K. Expected non-compliance to secondary prevention medications after PCI for other medical reasons
- Patients who completed standard duration of DAPT (1-3months) and followed by maintenance of single antiplatelet agent (aspirin or P2Y12 inhibitor) for at least 1 year from index procedure.

... and 1 more (see full listing online)

### Exclusion (14)

- Patients unable to provide consent
- Patients with acute myocardial infarction or unstable angina
- Patients with known intolerance to aspirin, P2Y12 inhibitors, or components of DCB
- Patients with indication of oral anticoagulant
- Patients with concomitant drug-eluting stent implantation during index PCI

... and 9 more (see full listing online)

## Locations (18 total)

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Korea University Ansan Hospital, Ansan, South Korea  
Keimyung University Dongsan Medical Center, Daegu, South Korea  
Gangneung Asan Hospital, University of Ulsan College of Medicine, Gangneung, South Korea  
... and 15 more locations

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<https://clinicaltrials.gov/study/NCT06742931>

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