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A study to evaluate the safety and feasibility of a new drug-coated balloon treatment for patients with coronary artery narrowing

Submission date
17/11/2025

Recruitment status
No longer recruiting

Registration date
20/11/2025

Overall study status
Completed

Last Edited
20/11/2025

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Coronary artery disease occurs when the blood vessels supplying the heart become narrowed, which can reduce blood flow. A drug-coated balloon is a special device that delivers medication directly to the artery to help keep it open without leaving a permanent implant. This study aims to assess whether a new drug-coated balloon (GENOSS DCB) is safe and effective for treating patients with newly developed coronary artery narrowing.

Who can participate?
Adults aged 19 years or older with a newly diagnosed narrowing of a coronary artery that requires balloon treatment during a heart procedure may be eligible. People who have recently had a major heart attack, have severe heart weakness, severe kidney disease, or certain complex artery stenosis will not be able to take part.

What does the study involve?
Participants undergo a standard heart procedure called percutaneous coronary intervention. The narrowed artery is first opened with a regular balloon. If this is successful, the study device (GENOSS DCB) is inflated for 60 seconds to deliver medication to the artery wall. Participants then receive standard heart medications and return for routine follow-up visits, including a repeat angiogram at 6 months to check how the artery has healed.

What are the possible benefits and risks of participating?
Participants may benefit from the treatment of their coronary artery narrowing without receiving a permanent stent. Risks are similar to those of routine balloon procedures and may include bleeding, temporary vessel injury, or discomfort. Some participants may not experience direct benefits, but their involvement can help improve future heart treatments for others.

Where is the study run from?
The study is conducted at Hallym University Kangnam Sacred Heart Hospital and Yonsei University Severance Hospital in South Korea.

When is the study starting and how long is it expected to run for?
January 2023 to December 2023.

Who is funding the study?
The study is supported as part of a health-industry collaborative project in Korea. No commercial company is directly funding this research.

Who is the main contact?
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Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Study information

Scientific Title
Clinical feasibility and safety of a novel paclitaxel-coated balloon using shellac and vitamin E excipient for the treatment of de novo coronary artery lesions: a prospective, single-arm pilot study

Study objectives
The study aims to evaluate the clinical feasibility, safety, and angiographic efficacy of the GENOSS paclitaxel-coated balloon using a shellac plus vitamin E excipient in patients with de novo coronary artery lesions. The primary objective is to assess in-segment late lumen loss at 6 months following drug-coated balloon angioplasty. Secondary objectives include evaluating changes in minimal lumen diameter, diameter stenosis, restenosis rate, and the incidence of major adverse cardiac events.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 01/01/2023, Hallym University Kangnam Sacred Heart Hospital Institutional Review Board (1 Singil-ro, Yeongdeungpo-gu, Seoul, 07441, Korea, South; + 82-2-829-5193; knsh_irb@hallym.or.kr), ref: 2022-12-001

2. Approved 01/01/2023, Yonsei University Health system, Severance Hospital Institutional Review Board (Yonsei University Health System, Severance Hospital 50-1 Yonsei-ro, Seodaemun-gu, Seoul, 03722, Korea, South; +82-2-2228-0415; irb@yuhs.ac), ref: 1-2022-0088

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Device feasibility, Treatment

Study type(s)

Health condition(s) or problem(s) studied
De novo coronary artery lesions requiring percutaneous coronary intervention

Interventions
Participants undergo percutaneous coronary intervention with the GENOSS paclitaxel-coated balloon, which contains paclitaxel 3 μg/mm² with a shellac plus vitamin E excipient. All eligible lesions are first pre-dilated with a standard balloon catheter sized 1:1 to the reference vessel diameter. If predilation is successful with residual stenosis ≤ 30% and TIMI flow grade 3, the GENOSS drug-coated balloon is inflated at nominal pressure for 60 seconds to deliver the antiproliferative drug to the vessel wall. No control or comparator treatment is used, as the study follows a single-arm design. Participants continue to receive standard medical therapy, including aspirin and a P2Y12 inhibitor, for up to 6 months after the procedure. Follow-up visits are performed at 1 month and 6 months, with repeat coronary angiography at 6 months to evaluate angiographic outcomes.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
GENOSS Paclitaxel-Coated Balloon (paclitaxel 3 μg/mm² with shellac plus vitamin E excipient)

Primary outcome(s)
1. In-segment late lumen loss measured using quantitative coronary angiography (QCA) of the change in minimal lumen diameter within the treated segment at 6 months after the index procedure

Key secondary outcome(s)
1. Minimal lumen diameter of the treated segment measured using quantitative coronary angiography (QCA) at baseline, post-pre-dilation, post-DCB, and 6 months after the index procedure

2. Diameter stenosis of the treated segment measured using quantitative coronary angiography (QCA) at baseline, post-pre-dilation, post-DCB, and 6 months after the index procedure

3. Binary restenosis rate (diameter stenosis ≥ 50%) measured using quantitative coronary angiography determining percentage diameter stenosis at 6 months after the index procedure

4. Major adverse cardiac events (cardiac death, myocardial infarction, target lesion revascularization, or target vessel revascularization) measured using clinical event adjudication based on standardized definitions at 6 months after the index procedure

Completion date
05/12/2023

Eligibility

Key inclusion criteria
1. Adults aged ≥ 19 years.
2. Patients with de novo coronary artery lesions requiring percutaneous coronary intervention.
3. Target vessel diameter between 2.0 mm and 4.0 mm on coronary angiography.
4. Successful predilation with residual stenosis ≤ 30% and TIMI flow grade = 3.
5. Ability and willingness to provide written informed consent.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
19 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
20

Key exclusion criteria
1. ST-segment elevation myocardial infarction (STEMI) within the previous 48 hours.
2. Cardiogenic shock or hemodynamic instability.
3. Left ventricular ejection fraction < 30%.
4. Severe renal impairment (eGFR < 30 mL/min/1.73 m²).
5. Known contraindication or suspected intolerance to paclitaxel, aspirin, or P2Y12 inhibitors.
6. Life expectancy less than 1 year due to non-cardiac comorbidities.
7. Pregnancy or lactation.
8. In-stent restenosis lesions.
9. Bypass graft lesions.
10. Chronic total occlusions (CTO).
11. Left main coronary artery disease.
12. Failure of predilation defined as residual stenosis > 30% or TIMI flow < 3 after balloon angioplasty.

Date of first enrolment
04/01/2023

Date of final enrolment
25/07/2023

Locations

Countries of recruitment
Korea, South

Sponsor information

Organisation
Korea Health Industry Development Institute

ROR
https://ror.org/00fdzyk40

Funder(s)

Funder type

Funder Name
Kangdong Sacred Heart Hospital, Hallym University

Alternative Name(s)

Hallym University Kangdong Sacred Heart Hospital

Funding Body Type
Government organisation

Funding Body Subtype
Other non-profit organizations

Location
Korea, South

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.1		20/11/2025	No	Yes
Participant information sheet	version 1.1		20/11/2025	No	Yes
Protocol file	version 1.1	14/10/2022	20/11/2025	No	No