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# Drug-coated balloon (Sequent Please Neo) vs drug-eluting stent treatment for acute ST-elevation myocardial infarction: a randomised trial

**Submission date**
15/07/2025

**Recruitment status**
Recruiting

**Registration date**
15/07/2025

**Overall study status**
Ongoing

**Last Edited**
21/10/2025

**Condition category**
Circulatory System

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

## Plain English summary of protocol

Background and study aims
The rapid treatment of patients with an acute heart attack (ST-elevation myocardial infarction [STEMI]) is well established in terms of its significant benefits. This is done using coronary angiography, where a catheter is inserted (usually) through the wrist with local anaesthetic. The catheter is passed up to the heart and a balloon is inflated at the point of the blockage to reopen it. Once the artery is opened, two potential options are available for trying to keep that artery open in the long term. This involves either implanting a drug-eluting stent (DES) or inflating a drug-coated balloon (DCB) at the point of this blockage. Whilst DES have been used for many years, it is now recognised that a significant number (2-4% per year) re-narrow over time and the physical presence of the stent is likely to contribute to this process. Therefore, many operators now use a DCB, which coats the vessel with an anti-proliferative drug to prevent further narrowing but avoids the need for stent implantation. A direct comparison of these two approaches has not been performed. This study will examine the safety and efficacy of DCB versus DES in patients admitted to hospital with a STEMI. The study will use CE-marked DCB and DES devices. All devices used in this clinical investigation will be used in compliance with their approved Instructions for Use and in accordance with standard clinical practice. This study aims to determine if drug-coated balloon treatment of coronary artery blockages during a STEMI (heart attack) provides an equivalent outcome to treatment with a drug-eluting stents (DES). This will be measured by the 1-year target vessel failure, which is a composite of cardiac death, further clinically-driven treatment of the target vessel or a further myocardial infarction (heart attack) caused by the target vessel.

Who can participate?
Patients with a STEMI which requires emergent percutaneous coronary intervention (PCI)

What does the study involve?
Participants are randomly allocated to one of two groups. One group will receive drug-coated balloon (DCB) treatment and the other will receive drug-eluting stent (DES) treatment. All

participants will receive appropriate medications before, during and after their treatment as per current guidelines and operator/hospital approach, and will be discharged according to hospital policies. No changes to their inpatient care are performed. Post-treatment investigations are as per current practice and guidelines, including blood sampling for troponin at 24 hours and assessment of left ventricular function with transthoracic echo before discharge. Written information regarding the study will be provided to the patient post-procedure and consent obtained for further participation before discharge from hospital, usually on day 1. Follow-up in-person examinations will be conducted in accordance with the usual practices of the participating hospital. Additional study-specific follow-ups will be conducted at 30 days, 1 year, 3 years, 5 years and 8 years via telephone and with a review of patient notes as required. During the follow-up telephone appointments, medical and medication history will be collected to assess if any endpoints or adverse events have occurred and the angina index will be assessed via a short questionnaire.

What are the possible benefits and risks of participating?
Both treatments offered are approved products for use within the UK. It is possible that there may be extra benefits to using the drug-coated balloon (DCB), but this will only be established by this study. The major potential benefit of DCB use during STEMI will be the lack of a permanent implant into the coronary vessel, potentially improving the long-term and very long-term clinical course by preventing the risk of stent re-stenosis. Additionally, DCB treatment can allow a shorter duration of antiplatelets, which would reduce the bleeding risk after a STEMI. Were a bypass ever to be indicated, the treated coronary segment could receive a graft, unlike a stented segment. There are no additional research risks.

Where is the study run from?
University Hospital Sussex NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
April 2025 to October 2034

Who is funding the study?
B. Braun Melsungen AG (Germany)

Who is the main contact?
Dr Scott Harfield, scott.harfield@nhs.net

# Contact information

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Scientific

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## Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Integrated Research Application System (IRAS)
356772

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
CPMS 68120

## Study information

### Scientific Title
Drug-coated balloon (Sequent Please Neo) vs drug-eluting stent treatment for acute ST-elevation myocardial infarction: a randomised trial

### Acronym
DCB STEMI

### Study objectives
Primary objectives:
The primary objective of this study is to determine if drug-coated balloon treatment of coronary artery blockages during an ST-segment elevation myocardial infarction (heart attack) provides an equivalent outcome to treatment with drug-eluting stents (DES). This will be measured by the 1-year target vessel failure, which is a composite of cardiac death, further clinically-driven treatment of the target vessel or a further myocardial infarction (heart attack) caused by the target vessel.

Secondary objectives:
To determine if there is a difference in the following factors between patients having drug-eluting stents (DES) or drug-coated balloons (DCB):

1. Pre-discharge LV function
2. Length of stay
3. Bleeding (BARC)
4. Non-cardiac death
5. Freedom from in-hospital composite of cardiovascular mortality, target vessel myocardial infarction, target vessel revascularisation, stroke and BARC 2/3/5 bleeding
6. Acute and subacute vessel closure/stent thrombosis
7. Contrast and radiation dose
8. Procedural time
9. Costs
10. Follow-up at 30 days, 1 year, 3 years and 5 years:
10.1. Target vessel failure
10.2. All-cause mortality
10.3. Non-cardiac mortality
10.4. Revascularisation of non-target vessel
10.5. Patient-oriented ARC-2 composite endpoint (all-cause mortality, any stroke, any MI, any revascularisation)
10.6. Symptom status
10.7. Bleeding event
10.8. Net-clinical benefit: freedom from target vessel failure and bleeding
11. Cost-effectiveness at 5 years

## Ethics approval required
Ethics approval required

## Ethics approval(s)
approved 24/09/2025, London – Brighton and Sussex REC (-, -, -, United Kingdom; +44 (0)207 104 8140; brightonandsussex.rec@hra.nhs.uk), ref: 25/LO/0630

## Study design
Randomized; Interventional; Design type: Treatment, Device, Complex Intervention

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Acute ST-elevation myocardial infarction

## Interventions
The study is an investigator-initiated, prospective, open-label, randomised, non-inferiority study.

The study will be conducted across multiple primary angioplasty (heart attack) centres within the UK.

The target population for this study includes adult patients presenting with ST-segment elevation myocardial infarction requiring primary angioplasty treatment.

Pre-procedure examinations, including the collection of medical and medication history, assessment of angina index, and current medication, are conducted in accordance with routine practice.

Patients who are included as part of the emergency consent process will be randomized (1:1) to one of two groups. One group will receive Drug Coated Balloon (DCB) treatment and the other will receive Drug Eluting Stent (DES) treatment.

All participants will receive appropriate medications before, during and after their treatment as per current guidelines and operator/hospital approach, and will be discharged according to hospital policies. No changes to their inpatient care are performed.

Post-treatment investigations are as per current practice and guidelines, including blood sampling for troponin at 24 hours and assessment of left ventricular function with transthoracic echo prior to discharge.

Written information regarding the study will be provided to the patient post-procedure and consent obtained for further participation prior to discharge from hospital, usually on day 1.

Follow-up in-person examinations will be conducted in accordance with the usual practices of the participating hospital. Additional study-specific follow-ups will be conducted at 30 days, 1 year, 3 years, 5 years and 8 years via telephone and with a review of patient notes as required. During the follow-up telephone appointments, medical and medication history will be collected to assess if any endpoints or adverse events have occurred and the angina index will be assessed via a short questionnaire.

The primary endpoint will be examined as intention to treat.

## Intervention Type
Procedure/Surgery

## Primary outcome(s)
Target vessel failure measured using a composition of cardiac death, target vessel revascularisation and target vessel myocardial infarction at 1 year

## Key secondary outcome(s))
1. Pre-discharge LV function, measured using a transthoracic echo at pre-discharge
2. Length of stay, measured using hospital admission duration
3. Bleeding measured using the BARC scale during inpatient admission and follow-up
4. Non-cardiac death, measured using the death certificate and determining non-cardiac death during inpatient admission
5. Acute and subacute vessel closure/stent thrombosis, measured using an angiogram during the inpatient admission
6. Contrast and radiation dose, measured during the procedure
7. Procedural time, measured during the procedure

Measured at follow-up at 30 days, 1 year, 3 years and 5 years:
1. Target vessel failure and presence of reintervention, measured using a composition of cardiac death, target vessel revascularisation and target vessel myocardial infarction during follow-up
2. All-cause mortality measured using COD information on a death certificate
3. Non-cardiac mortality measured using COD information on a death certificate
4. Revascularisation of the non-target vessel measured using an angiogram and PCI to the non-

target vessel
5. Net-clinical benefit: freedom from target vessel failure and bleeding measured using the BARC 3-5 bleeding scale

### Completion date
01/10/2034

## Eligibility

### Key inclusion criteria
This trial presents an all-comers design allowing broad inclusion and few exclusion criteria. Specifically, patients can be included if suffering from STEMI, which requires emergent percutaneous coronary intervention (PCI) via the primary angioplasty service. To meet the criteria of a STEMI, patients need to have:
1. Symptoms of myocardial ischemia lasting for ≥30 min
2. Definite ECG changes indicating STEMI: ST elevation of >0.1 mV in two contiguous limb leads or ≥0.2 mV in two contiguous precordial leads

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Key exclusion criteria
1. Prior PCI of the target vessel
2. Previous CABG
3. Recent (<2 months) history of significant bleeding
4. Cardiac arrest requiring intubation before PPCI
5. Known allergy or contraindication for aspirin, clopidogrel, prasugrel, fondaparinux and/or heparin
6. Life expectancy less than 12 months

### Date of first enrolment
13/10/2025

### Date of final enrolment
01/10/2027

## Locations

### Countries of recruitment
United Kingdom

England

Scotland

Wales

**Study participating centre**
**University Hospitals Sussex NHS Foundation Trust**
Worthing Hospital
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Worthing
United Kingdom
BN11 2DH

**Study participating centre**
**Norfolk and Norwich University Hospitals NHS Foundation Trust**
Colney Lane
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NR4 7UY

**Study participating centre**
**University Hospitals Dorset NHS Foundation Trust**
Management Offices
Poole Hospital
Longfleet Road
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BH15 2JB

**Study participating centre**
**Worcestershire Acute Hospitals NHS Trust**
Worcestershire Royal Hospital
Charles Hastings Way
Worcester
United Kingdom
WR5 1DD

**Study participating centre**

**St George's Healthcare Nhst**
Blackshaw Road
London
United Kingdom
SW17 0QT

**Study participating centre**
**Sheffield Teaching Hospitals NHS Foundation Trust**
Northern General Hospital
Herries Road
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United Kingdom
S5 7AU

**Study participating centre**
**University Hospitals of North Midlands NHS Trust**
Newcastle Road
Stoke-on-trent
United Kingdom
ST4 6QG

**Study participating centre**
**University Hospitals Bristol and Weston NHS Foundation Trust**
Trust Headquarters
Marlborough Street
Bristol
United Kingdom
BS1 3NU

**Study participating centre**
**Manchester University NHS Foundation Trust**
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

**Study participating centre**
**Nottinghamshire Healthcare NHS Foundation Trust**
The Resource, Trust Hq
Duncan Macmillan House

Porchester Road
Nottingham
United Kingdom
NG3 6AA

**Study participating centre**
**Golden Jubilee National Hospital**
Agamemnon Street
Clydebank
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G81 4DY

**Study participating centre**
**University Hospitals Birmingham NHS Foundation Trust**
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**Study participating centre**
**East Kent Hospitals University NHS Foundation Trust**
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**Study participating centre**
**Cwm Taf Morgannwg University Local Health Board**
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**Study participating centre**
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# Sponsor information

**Organisation**
University Hospitals Sussex NHS Foundation Trust

**ROR**
https://ror.org/03wvsyq85

# Funder(s)

**Funder type**
Industry

**Funder Name**
B. Braun Melsungen

**Alternative Name(s)**
B. Braun Melsungen AG

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
For-profit companies (industry)

**Location**
Germany

# Results and Publications

**Individual participant data (IPD) sharing plan**
The data-sharing plans for the current study are unknown and will be made available at a later date

**IPD sharing plan summary**
Data sharing statement to be made available at a later date

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |