ISRCTN16341009 https://doi.org/10.1186/ISRCTN16341009

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
Not yet recruiting

Registration date
15/07/2025

Overall study status
Ongoing

Last Edited
15/07/2025

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

Type(s)

Contact name
Dr Scott Harfield

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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)
Not yet submitted, London – Brighton and Sussex REC (+44 (0)207 104 8140; brightonandsussex.rec@hra.nhs.uk)

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
Target vessel failure measured using a composition of cardiac death, target vessel revascularisation and target vessel myocardial infarction at 1 year

Secondary outcome measures
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

Overall study start date
30/04/2025

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

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 700; UK Sample Size: 700

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
01/10/2025

Date of final enrolment
01/10/2027

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

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

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

Study participating centre
University Hospitals Dorset NHS Foundation Trust
Management Offices
Poole Hospital
Longfleet Road
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United Kingdom
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
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road
Sheffield
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
Greater Glasgow and Clyde
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
United Kingdom
G12 0XH

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Study participating centre
Ashford and St Peter's Hospitals NHS Foundation Trust
St Peters Hospital
Guildford Road
Chertsey
United Kingdom
KT16 0PZ

Study participating centre
Cwm Taf Morgannwg University Local Health Board
Dewi Sant Hospital
Albert Road
Pontypridd
United Kingdom
CF37 1LB

Sponsor information

Organisation
University Hospitals Sussex NHS Foundation Trust

Sponsor details
Worthing Hospital
Lyndhurst Road
Worthing
England
United Kingdom
BN11 2DH

Sponsor type
Hospital/treatment centre

Website
https://www.uhsussex.nhs.uk/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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