

# A clinical trial comparing how well two solutions protect the heart during heart surgery in children

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<b>Registration date</b> 28/07/2021	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 23/01/2026	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

This study aims to improve the outcomes of children's heart surgery so that they recover faster with fewer complications. Children with congenital heart defects often need operations to correct the abnormalities that they were born with. The surgery is complex and usually involves a period of support on a heart-lung machine (cardiopulmonary bypass). This allows the heart to be stopped for a short period of time, using a fluid called cardioplegia solution, whilst the defect is repaired. Inevitably, any surgery puts a strain on the heart and has the potential to cause damage. In this study, we will compare two types of cardioplegia solution used to stop the heart: del Nido, the most commonly used in children in the US, and St Thomas', currently the standard practice in the UK, to determine which solution protects the heart better, and whether children recover faster and with fewer complications, so that we can improve the outcomes of children's heart surgery.

### Who can participate?

Children aged less than 16 years who are undergoing heart surgery requiring cardioplegia.

### What does the study involve?

During the operation, the heart will need to be stopped for a period of time so that the surgeon can repair the heart defect. Being involved in this study will not affect whether the heart needs to be stopped during the operation – the only change will be the type of cardioplegia solution that is used. Both del Nido and St Thomas' cardioplegia solutions are in routine clinical use in hospitals around the world and have been used in many thousands of children's heart operations.

### What are the possible benefits and risks of participating?

This trial will increase our understanding of which cardioplegia is better in children but there may not be any direct benefit for a child taking part. Whilst some previous studies have suggested that del Nido cardioplegia may better protect children's hearts during surgery, we do not know if it is beneficial to all children and whether they recover faster with fewer complications - that is why we are conducting this study. We do not know whether being in the study will make your child's surgery safer, but we are conducting it to understand how to

improve the outcomes of children's heart surgery in the future. Both types of cardioplegia are used routinely for heart surgery in children, del Nido in the US and St Thomas' in the UK. The operation itself carries a risk, as discussed with the Surgeon and Cardiologist, but being involved in this study causes no additional pain, discomfort, distress or intrusion.

Where is the study run from?

This trial is being coordinated by the DESTINY trial office at Birmingham Clinical Trials Unit (BCTU) and is sponsored by the University of Birmingham (UK).

When is the study starting and how long is it expected to run for?

June 2021 to July 2025

Who is funding the study?

British Heart Foundation

Who is the main contact?

DESTINY trial office, DESTINY@trials.bham.ac.uk

## Contact information

### Type(s)

Scientific

### Contact name

Mr Nigel Drury

### ORCID ID

<https://orcid.org/0000-0001-9012-6683>

### Contact details

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United Kingdom  
B4 6NH  
+44 (0)121 3338731  
nigel.drury@nhs.net

## Additional identifiers

### Clinical Trials Information System (CTIS)

2021-001915-10

### Integrated Research Application System (IRAS)

279068

### ClinicalTrials.gov (NCT)

Nil known

**BHF grant code**

CS/20/3/34738

**Central Portfolio Management System (CPMS)**

49735

## Study information

**Scientific Title**

del Nido versus St. Thomas' blood cardioplegia in the young (DESTINY) trial: a multi-centre randomized controlled trial in children undergoing cardiac surgery

**Acronym**

DESTINY

**Study objectives**

To determine whether in children undergoing cardiac surgery, the use of del Nido cardioplegia, compared with St. Thomas' blood cardioplegia, will reduce myocardial injury during surgery.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 30/06/2021, West Midlands - Coventry & Warwickshire Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8009; coventryandwarwick.rec@hra.nhs.uk), ref: 21/WM/0149

**Study design**

Interventional randomized controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Cardiac surgery

**Interventions**

The trial interventions are either del Nido cardioplegia (experimental arm) or St. Thomas' blood cardioplegia (control arm). del Nido cardioplegia is administered in a 1:4 blood:crystalloid preparation, given at 4-8°C, with an initial dose of 20ml/kg and subsequent doses every 60-90 minutes if required, at the discretion of the surgeon, as required. St. Thomas' blood cardioplegia is administered in a 4:1 blood:crystalloid using Harefield Hospital preparation, given at 4-8°C, with an initial dose of 20-30ml/kg, subsequent doses of 15 ml/kg every 20-30 minutes at the discretion of the surgeon, as required.

Blood samples will be taken at several time-points: before the operation, once the child is asleep under anaesthesia; and at 5 timepoints after the operation, at 3, 6, 9, 12 and 24 hours after surgery.

Following surgery, the child will be transferred to the Paediatric Intensive Care Unit and will be closely monitored. Follow-up in the trial will be until 30 days after the index operation.

### **Intervention Type**

Procedure/Surgery

### **Primary outcome(s)**

Area under the time-concentration curve (AUC) for plasma high-sensitivity troponin-I ( $\mu\text{g}\cdot\text{h}/\text{L}$ ) in the first 24 hours after the index aortic cross-clamp release (reperfusion).

### **Key secondary outcome(s)**

Current secondary outcome measures as of 14/03/2024:

1. Low cardiac output syndrome (LCOS) defined as either of the following: Vasoactive Inotrope Score (VIS)  $\geq 15$ , or major cardiac event (cardiac arrest, ECLS or death) in the first 48 hours after reperfusion
2. Duration of mechanical ventilation (hours), defined as the number of hours from termination of index CPB to extubation
3. Length of postoperative stay on Paediatric Intensive Care (hours), defined as number of hours from admission to PICU from theatre following index procedure to discharge from PICU
4. Maximum VIS by thresholds:  $\geq 10$ ,  $\geq 15$  and  $\geq 20$  in the first 48 hours after reperfusion
5. Total VIS in the first 4 hours after PICU admission following the index procedure (score)
6. Arterial lactate (mmol/L) in the first 12 hours after reperfusion
7. Omega, determined by  $[\text{SaO}_2]/[\text{SaO}_2 - \text{ScvO}_2]$  in the first 12 hours after reperfusion
8. Total aortic cross-clamp time (mins) during the index procedure
9. Total volume of cardioplegia given (ml) during the index procedure
10. Need for internal defibrillation during reperfusion during the index procedure
11. Delayed sternal closure, incidence and duration (days) following the index procedure
12. Unplanned reoperation, including chest re-opening on PICU, following the index procedure
13. Need for new renal replacement therapy following the index procedure
14. Lowest estimated glomerular filtration rate (eGFR), calculated using the bedside Schwartz equation and the peak postoperative creatinine on routine monitoring during the first 7 days following the index procedure ( $\text{ml}/\text{min}/1.73\text{m}^2$ ), and according to the paediatric RIFLE categories
15. Length of postoperative stay in the hospital (days), defined as number of days from day of the index procedure to discharge from hospital or death, whichever is sooner
16. 30-day survival following the index procedure

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- from admission to PICU from theatre following index procedure to discharge from PICU
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**Completion date**

31/07/2025

## Eligibility

**Key inclusion criteria**

Children (<16 years) undergoing cardiac surgery on cardiopulmonary bypass with cardioplegic arrest

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

0 years

**Upper age limit**

16 years

**Sex**

All

**Total final enrolment**

112

**Key exclusion criteria**

Current exclusion criteria as of 18/03/2025:

1. Predicted cross-clamp time <30 minutes (e.g. atrial septal defect, atrial septectomy, sub-aortic stenosis) at the discretion of the Consultant surgeon
  2. Known contraindication to one of the constituents of either cardioplegia solution (e.g. lidocaine/procaine hypersensitivity/allergy) or its method of delivery, including temperature (e.g. haemoglobinopathy including sickle cell disease, cold agglutinins)
  3. Ventricular assist device (VAD) insertion/explant or transplantation
  4. Pre-operative inotropic support or extracorporeal life support (ECLS)
  5. Previous cardiac surgery with cardioplegic arrest within the last 30 days
  6. Previous enrolment in the DESTINY trial
  7. Emergency surgery
  8. Parent/guardian declines consent
  9. Weight at the time of screening >50 kg
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(added 15/03/2023)

8. Weight at the time of surgery >50 kg
9. Previous enrolment in the DESTINY trial

**Date of first enrolment**

07/02/2022

**Date of final enrolment**

13/03/2025

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre****Birmingham Children's Hospital**

Steelhouse Lane

Birmingham

England

B4 6NH

**Study participating centre****Bristol Royal Hospital for Children**

University Hospitals Bristol and Weston NHS Foundation Trust

Upper Mauldin Street

Bristol

England

BS2 8BJ

**Study participating centre****Great Ormond Street Hospital**

Great Ormond Street

London

England

WC1N 3JH

**Study participating centre****Leeds General Infirmary (Children's Hospital)**

The Leeds Teaching Hospitals NHS Trust

Great George Street

Leeds

England

LS1 3EX

**Sponsor information**

## Organisation

University of Birmingham

## ROR

<https://ror.org/03angcq70>

## Funder(s)

### Funder type

Charity

### Funder Name

British Heart Foundation

### Alternative Name(s)

The British Heart Foundation, the\_bhf, BHF

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Trusts, charities, foundations (both public and private)

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

Requests for access to data should be addressed to the Chief Investigator. Individual participant data collected during the trial (including the data dictionary) will be available, after deidentification, once published with no end date. All proposals requesting data access must specify how the data will be used, and all proposals will need the approval of the Trial Management Committee before data release.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		14/04/2025	16/04/2025	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No

<a href="#">Participant information sheet</a>	Child version 1.0	25/03/2021	28/07/2021	No	Yes
<a href="#">Participant information sheet</a>	Parent version 1.1a	06/07/2021	28/07/2021	No	Yes
<a href="#">Participant information sheet</a>	Parent version 1.1b	06/07/2021	28/07/2021	No	Yes
<a href="#">Participant information sheet</a>	Parent version 3.0a	05/10/2023	14/03/2024	No	Yes
<a href="#">Participant information sheet</a>	Parent version 3.0b	05/10/2023	14/03/2024	No	Yes
<a href="#">Participant information sheet</a>	Parent version 2.0a	27/08/2021	14/03/2024	No	Yes
<a href="#">Participant information sheet</a>	Parent version 2.0b	27/08/2021	14/03/2024	No	Yes
<a href="#">Protocol file</a>	version 1.0	26/05/2021	28/07/2021	No	No
<a href="#">Protocol file</a>	version 2.0	19/08/2021	14/03/2024	No	No
<a href="#">Protocol file</a>	version 3.0	22/08/2022	14/03/2024	No	No
<a href="#">Protocol file</a>	version 4.0	25/10/2023	14/03/2024	No	No
<a href="#">Protocol file</a>	version 5.0	14/02/2025	18/03/2025	No	No
<a href="#">Statistical Analysis Plan</a>	version 2.0		23/01/2026	No	No
<a href="#">Study website</a>		11/11/2025	11/11/2025	No	Yes