

Feasibility study for a Randomised Controlled Trial of CUstodiol-HTK vs St Thomas' solution for cardioplegia and cold static Storage of UK donor hearts in cardiac transplantation (F-CUSToS)

CTAG Heart



Blood and Transplant



UNIVERSITY OF
CAMBRIDGE



Royal Papworth Hospital
NHS Foundation Trust

Luke JL Williams (PhD Candidate, Girton College, Cambridge) - 25/03/2026

What?

Feasibility study for a Randomised Controlled Trial of Custodiol-HTK vs St Thomas' solution for cardioplegia and cold static Storage of UK donor hearts in cardiac transplantation (F-CUSToS)

- **PIs:**
 - Mr Marius Berman, Surgical Lead for Transplantation and Mechanical Circulatory Support, Royal Papworth Hospital
 - Mr Gavin Pettigrew, University Reader in Clinical and Experimental Transplantation, University of Cambridge
- **Design:** Single blind, prospective, multi-centre, national, randomised controlled feasibility study
- **Sample size:** 25 patients per arm (**n=50**)
- **Inclusion criteria:** All adults undergoing heart transplant from a DBD donor
- **Exclusion criteria:** Use of ex-situ or normothermic regional perfusion, age<18, emergency re-transplant within index admission
- **Intervention:** Custodiol HTK
- **Control:** St Thomas' solution
- **Outcomes:** Consent rate >50%; proportion receiving correct intervention; data completion; Primary graft dysfunction, 30-day mortality, length of stay; post-operative complications

How?

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- Sponsored by Papworth R+D
- Funded by Heart Research UK
- Randomisation performed centrally via SealedEnvelope
- Each NORS team to take both solutions to all DBD Heart retrievals
- Standard protocols for delivery of each solution:
 - Custodiol: at least 3.5L over at least 10 minutes. Heart goes into bag with 2L Custodiol, not saline.
 - St Thomas' solution: Standard NORS protocol

Recruitment

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Site	Consented	Enrolled
<i>Birmingham</i>	21	1
<i>Glasgow</i>	5	1
<i>Harefield</i>	5	3
<i>Manchester</i>	21	4
<i>Newcastle</i>	21	2
<i>Papworth</i>	25	9
<i>Total</i>	98	20