

# Cold Pulsatile Perfusion in Asystolic donor Renal Transplantation

<b>Submission date</b> 31/03/2005	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/05/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/02/2016	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Kidneys from deceased organ donors need to be preserved out of the body to allow time for them to be allocated to a recipient, transported to the recipient centre, and for the recipient to be brought in and prepared for surgery. Typically this takes 12 to 18 hours. Traditionally preservation has been achieved by simply flushing the kidneys with a special preservation solution and placing them in a container of ice. An alternative is to put the kidney on a machine to continuously flush preservation fluid through the kidney until it is time to transplant the kidney into a recipient. The aim of this study is to see which method is superior for kidneys donated by deceased organ donors after circulatory death (DCD).

### Who can participate?

Patients aged 18 and over undergoing transplantation of a kidney from a deceased organ donor.

### What does the study involve?

Donated kidneys are randomly allocated such that one kidney of a pair is placed on the perfusion machine while the other is flushed and stored in ice until transplantation. Both kidneys of a pair are transplanted at the same centre. The transplant recipients are then followed up to see whether the kidney worked immediately or whether there was a delay in it starting normal function – around half of kidneys from DCD donors do not work immediately and the recipient needs to continue on dialysis until it does work.

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

Not provided at time of registration

### Where is the study run from?

Addenbrooke's Hospital (UK)

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

August 2006 to February 2009

### Who is funding the study?

Novartis Pharmaceuticals and Organ Recovery Systems

Who is the main contact?  
Mr Christopher Watson

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mr Christopher Watson

**Contact details**  
Department of Surgery  
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Hills Road  
Cambridge  
United Kingdom  
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## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**  
A multicentre randomised controlled study of cold Pulsatile Perfusion in Asystolic donor Renal Transplantation

**Acronym**  
PPART

**Study objectives**  
Primary objective:  
To evaluate the effect of machine perfusion on the incidence of primary function post renal transplantation.

Secondary objective:  
To evaluate the cost effectiveness of machine perfusion in asystolic donor kidney transplantation.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
The London Research Ethics Committee (REC), 02/02/2006, ref: 05/MRE02/74). Last ethics progress report dated 05/03/2008: favourable ethical opinion given 19/03/2008.

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Kidney preservation prior to transplantation

**Interventions**

Machine perfusion of the kidney before transplantation versus simple cold storage

**Intervention Type**

Procedure/Surgery

**Phase**

Not Applicable

**Primary outcome(s)**

1. Incidence of delayed graft function (need for dialysis in the first 7 days)
2. Calculated glomerular filtration rate (GFR) (MDRD technique) at 7 days

**Key secondary outcome(s)**

1. Patient survival
2. Graft survival
3. Renal function measured using calculated GFR
4. Never function rate
5. Time to last dialysis post transplant
6. Acute rejection incidence
7. Cost comparison at one and five years

**Completion date**

28/02/2009

**Eligibility****Key inclusion criteria**

Subjects (aged 18 years and over, either gender) undergoing transplantation of a kidney from a non-heart-beating (asystolic) cadaver organ donor.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

Added 24/02/2009:

1. Lack of informed consent
2. Positive cross-match
3. Previous recipient of non-renal transplant

**Date of first enrolment**

18/08/2006

**Date of final enrolment**

28/02/2009

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Addenbrooke's Hospital**

Cambridge

United Kingdom

CB2 2QQ

## Sponsor information

**Organisation**

Addenbrooke's Hospital (UK)

**ROR**

<https://ror.org/055vbx86>

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

Addenbrooke's Hospital (UK) - transplant research fund

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/09/2010		Yes	No