Direct procurement (DP) and hypothermic oxygenated perfusion (HOPE) of donor hearts after circulatory death (DCD) using the XVIVO Heart Assist Transport System

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Primary objective:To evaluate patient survival after direct procurement and hypothermic oxygenated machine perfusion of DCD donor hearts using the XVIVO Heart Assist Transport System.Secondary objective(s):The secondary objectives are to evaluate...

Ethical review	Approved WMO
Status	Pending
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON57060

Source
ToetsingOnline

Brief title
HOPE at Heart - XVIVO Heart Transplant study

Condition

- Heart failures

Synonym
End-stage heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Clinical Affairs
Source(s) of monetary or material Support: XVIVO Perfusion AB

Intervention

Keyword: Direct procurement, Donor hearts after circulatory death, Heart transplantation, Hypothermic oxygenated perfusion

Outcome measures

Primary outcome

The primary endpoint is defined as patient survival at 30 days post-transplant.

Secondary outcome

Secondary endpoints at 30-days post-transplant

1. Cardiac related mortality at 30 days post-transplant

2. Incidence of Mechanical circulatory support within 30 days post-transplant

3. Incidence of severe Primary Graft Dysfunction (PGD) at 24 hours

post-transplant (Kobashigawa et al., 2014)

4. Cardiac function as assessed by left ventricular ejection fraction (LVEF) at

24 hours and 30 days post-transplant

5. Incidence of hearts perfused on the investigational device which are not

used for transplantation

6. Total duration of ICU stay (days)

7. Incidence of biopsy proven rejections > 1 ACR (leading to changed

immunosuppressive regime) within 30 days post-transplant

Secondary endpoints at 6 months post-transplant

8. Cardiac related mortality at 6 months post -transplant

9. Cardiac function as assessed by left ventricular ejection fraction (LVEF) at

6 months post-transplant

10. Number of days until hospital discharge from index procedure

11. Incidence of biopsy proven rejections > 1 ACR leading to changed

immunosuppressive regime within 6 months post-transplant

Exploratory endpoints

12. Cardiac biopsy collected before reperfusion (optional and only if in

clinical routine)

Study description

Background summary

Study rationale:
Clinical investigation to support the use of direct procurement (DP) of donor hearts in donation after circulatory death (DCD) followed by hypothermic oxygenated perfusion using the XVIVO Heart Assist Transport System. Thereby increasing the utilization of DCD donor hearts heart in donation after circulatory death.

Hypothesis:
The hypothesis is that the use of DP-HOPE in DCD heart transplantation is safe and feasible.

Study objective

Primary objective:
To evaluate patient survival after direct procurement and hypothermic oxygenated machine perfusion of DCD donor hearts using the XVIVO Heart Assist Transport System.

Secondary objective(s):
The secondary objectives are to evaluate patient outcomes and graft function post-transplant.

Study design

Prospective, single-arm, multicentre, multinational proof-of-concept study.

Intervention

Heart transplantation.

Study burden and risks

There are no extra interventions (apart from the use of the XVIVO Heart Assist Transport System for donor heart procurement) associated with participation in the study. All clinical procedures are performed according to standard clinical care at the participating sites and the medical needs of each subject. There are no extra interventions for the study subjects.

A patient receiving a donor heart perfused with XVIVO Heart Assist Transport System may experience the same kind of adverse events and post-transplant complications as those experienced with any heart transplant. The following clinically relevant residual risks have been identified:
• Systemic infection
• Irreversible injury to the donor heart, heart not transplanted.
• Injury to the donor heart - Heart transplanted (Reversible, e.g. mild PGD; Moderate, e.g. temporarily reduced cardiac function, cardiac arrythmia, cardiac tamponade, moderate PGD, allograft rejection; or Major injury, e.g. cardiac arrest, myocardial infarction, severe PGD, ventricular fibrillation, aortic injury, multiorgan failure, septic shock)
• Anaphylactic, allergic or toxic reactions

While these risks have been identified as associated with the XVIVO Heart Assist Transport system, the same severe risks are associated with heart transplantation in general, regardless of the method used to preserve the donor heart. This includes *systemic infection* and *injury to the donor heart*, since any invasive procedure carries a risk of infection, and there is always a risk of receiving a heart that does not function properly after transplantation.

The residual risk of anaphylactic, allergic or toxic reactions is related to components of the solution (i.e. Human serum albumin (HSA) and dextran). During heart transplantation the patient is under extensive monitoring in an operating room. In the unlikely event of an anaphylactic reaction this would be noted instantly and the patient would be treated immediately under extensive surveillance. When administered systemically, HSA has been associated with rare allergic reactions (<1 in 1000) such as urticaria, fever, chills, pruritus and anaphylaxis. Dextran has also been associated with rare anaphylactic reactions (<1 in 1000); however, no such reactions have been reported with either of

these substances when used for ex vivo organ perfusion/preservation and subsequently transplanted. Interactions with concomitant medication
There are no known interactions with concomitant medication.

The risks related to the use of the XVIVO Heart Assist Transport System are weighed against the benefit of facilitating DCD heart procurement and increasing the donor pool. The benefit of increasing the number of donor hearts available without compromising the patient outcomes ultimately reduces waitlist mortality. When weighed together, a positive benefit/risk ratio of the XVIVO Heart Assist Transport System has been demonstrated.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Inclusion - Heart donor

1. Accepted as a heart donor by the transplant team based on current standard of care criteria
2. DCD Maastricht category III and euthanasia donors
3. Age <= 60 years old

Inclusion Recipient
1. Age >=18 years
2. Signed informed consent form
3. Accepted or listed for heart transplantation

Exclusion criteria

Exclusion - Heart Donor
1. Functional warm ischemia time (FWIT) > 30 minutes.
2. Donor cardiac arrest does not occur within 120 minutes from Withdrawal of life sustaining therapy (WLST)
3. Deviations from Donor end of life treatment protocol as defined by local standard operating procedures
4. Donor heart assessed as not transplantable by the responsible clinician at any time point during the donation or procurement procedure

Exclusion Recipient
1. Not able to understand the information provided during the informed consent procedure
2. Previous solid organ transplantation
3. Grown-up congenital heart disease (GUCH)
4. Dialysis
5. Incompatible blood group
6. Combined organ transplantation candidates
7. Subjects under pre-transplant desensitization protocol (including plasma exchange in conjunction with the transplant surgery)
8. Mechanical circulatory support at time of transplantation (except durable Left ventricular assist device or Intra-aortic balloon pump)

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	13-09-2024
Enrollment:	15
Type:	Anticipated

Medical products/devices used

Generic name:	XVIVO Heart Assist Transport System
Registration:	No

Ethics review

Approved WMO

Date:	24-10-2024
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL86559.000.24

Register	ID
Other	Not available yet