

# Injectable valve implantation trial (Invite)

|                                        |                                                   |                                                                                                              |
|----------------------------------------|---------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>20/01/2016   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>20/01/2016 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results            |
| <b>Last Edited</b><br>02/06/2023       | <b>Condition category</b><br>Circulatory System   | <input type="checkbox"/> Individual participant data                                                         |

## Plain English summary of protocol

### Background and study aims

Congenital heart disease (CHD) is the general term used to describe a range of birth defects that affect the heart. The majority of children born with a congenital heart defect (CHD) now live into adulthood. Many of them need repeated operations throughout life to replace the valves on the right side of the heart (pulmonary valves). The standard operation for valve replacement involves opening the chest so that the heart is accessible to the surgeon and the use of the heart lung machine to take over the function of the heart and lungs (pumping blood and oxygen through the body) during the operation. It has been found however, that repeated use of the heart lung machine is associated with complications, such as excessive bleeding, heart damage, stroke, and even death, and so it is preferable to avoid using them if possible. In recent years, new types of "injectable" self-expanding artificial valves have been developed for pulmonary valve replacement (PVR) procedures. They have been developed so they can be "injected" into position with the heart still beating (avoiding the need to use the heart lung machine) and without a need for the surgeon to fully expose the heart. The aim of this study is to find out if using injectable valves leads to a quicker recovery and shorter stay in hospital, saving money for the NHS, and whether they work as well as standard valves.

### Who can participate?

Patients aged between 12 and 80 who are having a PVR procedure.

### What does the study involve?

Participants are randomly allocated to one of two groups. Participants in the first group have the conventional PVR procedure, involving opening the chest to replace the affected valve, while using the heart lung machine to keep the patient alive during the operation. Participants in the second group have a PVR procedure using an injectable self-expanding valve is used. This involves the replacement valve being placed in the correct position through a small incision (cut). The length of time that the participants stayed in hospital after their operation is recorded for all participants.

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

Not provided at time of registration

### Where is the study run from?

Clinical Trials and Evaluation Unit, Bristol Royal Infirmary (UK)

When is the study starting and how long is it expected to run for?  
February 2016 to February 2018

Who is funding the study?  
National Institute for Health Research (UK)

Who is the main contact?  
Miss Rachel Heys

## Contact information

**Type(s)**  
Public

**Contact name**  
Miss Rachel Heys

**Contact details**  
Clinical Trials and Evaluation Unit  
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Bristol Royal Infirmary  
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## Additional identifiers

**Protocol serial number**  
20472

## Study information

**Scientific Title**  
The effectiveness on post-operative recovery of using 'off pump' self-expanding tissue valves versus 'on pump' conventional tissue valves for pulmonary valve replacement: An early phase randomised controlled trial

**Acronym**  
INVITE

**Study objectives**  
The aim of this study is to determine whether the use of injectable valves results in quicker recovery and shorter stay in hospital and is cost-saving for the NHS, and whether these valves function as well as the conventional ones.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

NRES Committee South West – Exeter, 16/11/2015, ref: 15/SW/0179

**Study design**

Randomised; Interventional; Design type: Treatment

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Topic: Children, Cardiovascular disease; Subtopic: All Diagnoses, Cardiovascular (all Subtopics); Disease: All Diseases, Congenital Heart Disease and Pulmonary Hypertension

**Interventions**

Eligible patients requiring PVR who give written informed consent to participate, will be randomised in a 1:1 ratio. Randomisation will be carried out using an internet-based system.

Group 1:: Participants receive an injectable pulmonary (BioPulmonic™, Biointegral Surgical Inc.) tissue valve inserted through a median sternotomy, without CPB.

Group 2: Participants receive a standard pulmonary stented tissue valve inserted through a median sternotomy with CPB.

Apart from the use of the intervention (IPVR) the patient care pathway will be as standard care.

Participants will be blinded to their treatment allocation until their participation in the trial has ended. The success of blinding will be monitored during each participant's follow up, and instances of unblinding will be recorded. Patients will be followed up for 6 months.

**Intervention Type**

Other

**Primary outcome(s)**

Chest drainage in the first 24 post-operative hours.

**Key secondary outcome(s))**

1. Post-operative time-to-'readiness for extubation'. The criteria below will be documented at the time of extubation (when all criteria should be met): normal temperature, cardiovascular system stable, no metabolic imbalance, blood loss decreasing and below a defined rate, able to clear respiratory secretions, patient awake, no residual muscle paralysis and adequate analgesia.
2. Length of ICU stay
3. Inotropic/vasodilator support
4. Chest drain volume in the first 0-12 hours
5. Blood products used in the first 24 hours
6. FFD, defined as all of: normal temperature, pulse and respiration, normal oxygen saturation on air, normal bowel function, physically mobile
7. Cardiac MRI assessment of valve and heart function at 6 months, defined as: presence and degree of pulmonary regurgitation, end-diastolic volume and right ventricular ejection fraction

8. Echocardiography assessment of valve function at routine follow-up at 6 months, defined as presence and degree of pulmonary regurgitation and residual valve stenosis, measured as peak velocity through the valve
9. Health-related quality of life is measured using the EuroQol EQ-5D (or EQ-5D-Y in patients <18 years), SF36 (in patients >18 years) and child health questionnaire (CHQ, in patients <18 years) at 6 weeks, 6 months
10. Valve-related complications during follow-up

**Completion date**

01/07/2020

## Eligibility

**Key inclusion criteria**

1. Patients undergoing either:
  - 1.1. Pulmonary valve replacement (PVR) or
  - 1.2. Pulmonary valve replacement (PVR) with PFO closure that would not require CPB if using an injectable valve or
  - 1.3. Pulmonary valve replacement (PVR) with RVOT reconstruction that does not require CPB if using an injectable valve
2. Patients aged 12–80 years old inclusive, with an adult valve size (25-31mm)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Sex**

All

**Total final enrolment**

19

**Key exclusion criteria**

1. Prisoners and adults lacking capacity to consent
2. Patients aged 12 to 15 years old under the care of social services
3. Patients with pulmonary valve or artery stenosis requiring patch reconstruction of the pulmonary arteries using CPB
4. Patients having an intra-cardiac shunt that would require CPB despite using an injectable valve
5. Patients having a RVOT reconstruction that would require CPB despite using an injectable valve
6. Patients requiring other anatomical heart corrections that would require CPB despite using an injectable valve
7. Patients who are unwilling to undergo surgery involving a porcine product
8. Patients unable to provide assent/consent

**Date of first enrolment**

01/02/2016

**Date of final enrolment**

14/10/2018

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre****Bristol Royal Infirmary**

Clinical Trials and Evaluation Unit

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Upper Maudlin Street

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## **Sponsor information**

**Organisation**

University of Bristol

**ROR**

<https://ror.org/0524sp257>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

National Institute for Health Research

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## Results and Publications

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

The datasets generated and analysed during this study will be stored in a publicly available repository: <https://data.bris.ac.uk/data/>, for all participants who consented for their data to be shared for future ethically approved research. Individual de-identified participant data, associated metadata, and additional related documents (e.g. statistical analysis plan) will be available after the publication of the main results of the study, indefinitely. Requests for data access will be reviewed by the appropriate University of Bristol data access committee. The requirements for access include; an affiliated institution; ethical approval; and evidence of any funding and/or sponsorship.

**IPD sharing plan summary**

Stored in publicly available repository

**Study outputs**

| Output type                          | Details  | Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------------------------------|----------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>      | protocol | 01/06/2023   | 02/06/2023 | Yes            | No              |
| <a href="#">Protocol article</a>     |          | 02/04/2019   | 10/05/2019 | Yes            | No              |
| <a href="#">HRA research summary</a> |          |              | 28/06/2023 | No             | No              |