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Injectable valve implantation trial (Invite)

Submission date 20/01/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/01/2016	**Overall study status** Completed	
Last Edited 02/06/2023	**Condition category** Circulatory System	

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Chest drainage in the first 24 post-operative hours.

Secondary outcome measures
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

Overall study start date
01/06/2014

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

Age group
Mixed

Sex

Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

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
England

United Kingdom

Study participating centre
Bristol Royal Infirmary
Clinical Trials and Evaluation Unit
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Sponsor information

Organisation
University of Bristol

Sponsor details
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Sponsor type
University/education

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

Publication and dissemination plan
1. Planned presentation of study results at international meetings
2. Planned publication in peer reviewed publications

3. Planned dissemination through patient organisations and newsletters to patients, where available

Intention to publish date
01/07/2021

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?
Protocol article	protocol	02/04/2019	10/05/2019	Yes	No
Results article		01/06/2023	02/06/2023	Yes	No
HRA research summary			28/06/2023	No	No