

# Outcome monitoring after cardiac procedure in congenital heart disease

<b>Submission date</b> 28/05/2019	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 01/07/2019	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 31/05/2024	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Despite congenital heart disease (CHD) being the most common birth defect affecting between 0.4 -1.2% of live-born children in developed countries, the potential causal molecular, genetic and environmental risk factors are not well understood. Pressure on paediatric and adult services to support CHD survivors is increasing and the development of information integration tools to help prevention as well as outcome prediction following a cardiac procedure is one of the most prominent challenges of clinical cardiology. This study aims to develop a CHD data registry of patients undergoing surgery and/or catheterisation.

### Who can participate?

Children (0-15 years old) or young adults (16 – 18 years of age), with CHD undergoing surgery and /or catheterization, and their biological mothers

### What does the study involve?

The researchers obtain consent from participants to add routinely collected clinical data to their registry. They also ask patients to complete a short quality of life questionnaire three times: during their hospital stay and then at 3 and 12 months after the procedure. Participants are given a choice of completing questionnaires online or by post to maximise convenience and for economic and environmental reasons. In addition, the researchers ask for consent to use tissue and fluid that is usually removed during surgery and discarded, and to collect up to three blood and three urine samples specifically for research. These samples are stored for future analyses to identify potential markers of post-operative complications and recovery. Participant's biological mothers are invited to consent to relevant data from their pregnancy medical notes to be added to the study's registry. Mothers are also asked to provide one blood and one urine sample and to complete a maternal risk factors questionnaire to contribute to a better understanding of potentially modifiable maternal risk factors in the context of CHD prevention. Bio-samples are banked for future analyses to characterise patients and their mothers phenotypically and genetically. Where consent has been obtained, pseudonymised samples may be made available to future Research Ethics Committee (REC) approved studies. This is an efficient and cost-effective method of obtaining information that can be used to evaluate promising interventions in the longer-term and to provide data for observational studies, characterising longer-term outcomes of translational research.

What are the possible benefits and risks of participating?

The main benefit will be to provide information that may lead to improvements in the patient's care and quality of life in the future. All samples (blood and urine) will be collected through lines that will be in place as part of standard care and therefore there are no additional risks to the patient in this respect. The only potential risk is that of reminding patients of a time that was stressful and perhaps difficult for them when the study sends the follow-up questionnaires. However, in the researchers' experience the majority of participants do appreciate the additional contact. Regarding the mothers, there is a very minimal risk associated with blood withdrawal. Adverse events will be recorded and reported in accordance with University Hospitals Bristol's Research Safety Reporting SOP.

Where is the study run from?

Bristol Royal Hospital for Children (BRHC) (UK)

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

June 2019 to August 2030

Who is funding the study?

British Heart Foundation (UK)

Who is the main contact?

Mai Baquedano

mai.baquedano@bristol.ac.uk

## Contact information

### Type(s)

Scientific

### Contact name

Ms Gianni Angelini

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

158780 - University of Bristol

## Study information

**Scientific Title**

Outcome monitoring and risk stratification after cardiac procedure in neonates, infants, children and young adults born with congenital heart disease

**Acronym**

Children OMACp

**Study objectives**

To compile a data registry of patients with CHD undergoing surgery and/or catheterisation, bringing together routinely collected clinical data, as well as collecting bio-samples (blood, urine and waste tissue when appropriate) in order to characterise patients and their biological mothers genetically and phenotypically.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 30/07/2019, NHS REC South West – Central Bristol (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; +442071048046; nrescommittee.southwest-bristol@nhs.net), ref: 19/SW/0113

**Study design**

Single-centre prospective cohort study

**Primary study design**

Observational

**Secondary study design**

Cohort study

**Study setting(s)**

Hospital

**Study type(s)**

Other

**Participant information sheet**

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

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

Congenital heart disease

## **Interventions**

This study aims to develop a CHD data registry of patients undergoing surgery and/or catheterisation. The researchers propose to obtain consent from participants to add routinely collected clinical data to their registry. They will also ask patients to complete a short quality of life questionnaire three times: during their hospital stay and then at 3- and 12-months post procedure. Participants will be given a choice of completing questionnaires online or by post to maximise convenience and for economic and environmental reasons. In addition, the researchers will ask for consent to use tissue and fluid that is usually removed during surgery and discarded, and to collect up to three blood and three urine samples specifically for research. These samples will be stored for future analyses to identify potential markers of post-operative complications and recovery.

The researchers will invite the participants' biological mothers to consent to relevant data from their pregnancy medical notes to be added to the study's registry. Mothers will also be asked to provide one blood and one urine sample and to complete a maternal risk factors questionnaire to contribute to a better understanding of potentially modifiable maternal risk factors in the context of CHD prevention. Bio-samples will be banked for future analyses to characterise patients and their mothers phenotypically and genetically. Where consent has been obtained, pseudonymised samples may be made available to future Research Ethics Committee (REC) approved studies.

## **Intervention Type**

Other

## **Primary outcome measure**

1. Aggregated routinely collected clinical data from review of medical notes: operation /catheterisation, PICU, HeartSuite, Hospital episode statistics (HES), HER, Magnetic Resonance Imaging (MRI), Computerised tomography (CT), Echocardiogram (ECHO). Assessed at baseline and then yearly for 5 years (with the option to extend to 10 years if further funding becomes available)
2. Phenotypic and genetic analysis of biomaterials that would normally be discarded during cardiac surgery (e.g. pericardial fluid, pieces of heart tissue and vessel removed during the operation) as well as blood and urine samples from patients and their biological mothers. Bio-samples will be stored long-term in the Bristol Biomedical Laboratory in preparation for future analyses by the children OMACp study or other ethically approved studies. Mothers and catheter patients: baseline blood and urine samples; surgery patients: baseline blood, urine and tissue when available, on arrival to PICU: blood and urine samples, 24 hours post-surgery: blood and urine samples

## **Secondary outcome measures**

1. Short, medium and long-term clinical outcomes in patients born with CHD undergoing cardiac surgery or catheter intervention, monitored by reviewing the patient's medical notes yearly for 5 years (with the option to extend to 10 years if further funding becomes available)
2. NHS resource use, monitored by reviewing the patient's medical notes yearly for 5 years (with the option to extend to 10 years if further funding becomes available)
3. Demographics collected via questionnaires at baseline
4. Patient's quality of Life (QoL) measured using KIDSCREEN/EQ5D-Y at baseline, 3 months and 12 months post-procedure
5. Maternal demographics and information on potentially modifiable risk factors associated with CHD, assessed using questionnaire developed specifically for this study and accessing relevant pregnancy medical records at baseline

6. Genetic and phenotypical characterisation of patients and their mothers
7. MicroRNA analyses and isolation of progenitor cells when sufficient tissue, plasma and serum are available

**Overall study start date**

01/06/2019

**Completion date**

31/08/2030

## Eligibility

**Key inclusion criteria**

Current inclusion criteria as of 31/05/2024:

Patients:

'Children (0-15 years old) or young adults (16 – 18 years of age), with CHD undergoing surgery and/or catheterisation OR having repeat surgery having been included in one of the groups mentioned above

Mothers:

Biological mother of a child enrolled in Children OMACp

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Previous inclusion criteria:

Patients:

Children (0-15 years old) or young adults (16 – 18 years of age), with CHD undergoing surgery and /or catheterisation

Mothers:

Biological mother of a child enrolled in Children OMACp

**Participant type(s)**

Mixed

**Age group**

Mixed

**Lower age limit**

0 Years

**Upper age limit**

15 Years

**Sex**

Both

**Target number of participants**

Patients: 4000 Mothers: 2000

**Key exclusion criteria**

1. Unable to give informed consent and/or assent
2. Main residence is outside the UK
3. Under the care of Social Services

**Date of first enrolment**

01/09/2019

**Date of final enrolment**

31/05/2029

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Bristol Royal Hospital for Children (BRHC)**

Upper Maudlin St

Bristol

United Kingdom

BS2 8BJ

**Study participating centre**

**Children's Research Team Leicester Royal Infirmary**

Infirmary Square

Leicester

United Kingdom

LE1 5WW

**Sponsor information****Organisation**

University Hospitals Bristol NHS Foundation Trust

**Sponsor details**

Education & Research Centre Level 3

Upper Maudlin Street

Bristol

England

United Kingdom  
BS2 8AE  
+44 (0)1173420233  
r&dsponsorship@uhbristol.nhs.uk

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.uhbristol.nhs.uk/research-innovation/>

**ROR**

<https://ror.org/04nm1cv11>

## Funder(s)

**Funder type**

Charity

**Funder Name**

British Heart Foundation

**Alternative Name(s)**

the\_bhf, The British Heart Foundation, BHF

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

The findings will be disseminated by usual academic channels, i.e. presentation at international meetings, as well as by peer-reviewed publications and through patient organisations and newsletters to participants, where available.

**Intention to publish date**

31/12/2030

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

The datasets generated during and/or analysed during the current study will be stored in NHS Trust internal servers. Pseudonymised data will be made available for sharing for secondary research, conditional on assurance from the secondary researcher that the proposed use of the data is compliant with the MRC Policy on Data Preservation and Sharing regarding scientific quality, ethical requirements and value for money. A minimum requirement with respect to scientific quality will be a publicly available pre-specified protocol describing the purpose, methods and analysis of the secondary research, e.g. a protocol for a Cochrane systematic review. A second file containing participant identifiers would be made available for record linkage or a similar purpose, subject to confirmation that the secondary research protocol has been approved by a UK REC or other similar, approved ethics review body. Requests for data to be made to Prof. Massimo Caputo (children-omacp@bristol.ac.uk). Where participants have consented to be contacted for future research, their contact details will be shared with studies that have obtained ethical approval. Data will be shared either through internal NHS services or encrypted, if externally.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			26/07/2023	No	No
<a href="#">Protocol article</a>		08/08/2023	09/08/2023	Yes	No