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Outcome monitoring after cardiac procedure in congenital heart disease

Submission date 28/05/2019	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 01/07/2019	**Overall study status** Ongoing	
Last Edited 31/05/2024	**Condition category** Circulatory System	

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

ORCID ID
http://orcid.org/0000-0002-7101-3082

Contact details
Level 7, Queen's Building, BRI
Upper Mauldin Street
Bristol
United Kingdom
BS8 2PS
+44 (0)1173423512
mai.baquedano@bristol.ac.uk

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
Brsitol
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?
HRA research summary			26/07/2023	No	No
Protocol article		08/08/2023	09/08/2023	Yes	No