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Causes of brain injury during heart surgery

Submission date	Recruitment status	[_] Prospectively registered
27/11/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/11/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/07/2020	Circulatory System	

Plain English summary of protocol

Background and study aims
Brain injury is a well known risk of heart surgery, but the exact causes are poorly understood. The aim of this study is to detect new brain injuries following heart surgery using an MRI brain scan, and by asking patients to perform a series of puzzles and language tasks assessing memory and brain function. Tests will be performed before and after surgery for comparison with the patients' medical records and type of surgery to help identify the causes of brain injury.

Who can participate?
Patients having heart surgery can join the study if it is safe for them to have an MRI scan, and their level of English is sufficient to complete the language tasks.

What does the study involve?
The study involves having an MRI brain scan lasting around 30 mins, and undergoing a series of puzzles and tests lasting approximately 1 hour. The brain scan and tests are performed twice: before the operation, and then 6-8 weeks afterwards. This will allow the study team to confidently identify new brain injuries. Patients also receive monitoring of brain blood flow during surgery using ultrasound, and we will obtain information about the patient's risk factors and type of surgery from medical records to explore potential causes of brain injury.

What are the possible benefits and risks of participating?
The MRI and ultrasound monitoring methods used in this study are low-risk and not harmful. If the brain MRI scan reveals any unexpected medical problems we will notify the patient's doctor. Otherwise, there are no direct benefits to the patient, although the results of our research may benefit patients in the future.

Where is the study run from?
This study takes place at Leicester Glenfield Hospital.

When is the study starting and how long is it expected to run for?
September 2010 to December 2014

Who is funding the study?
The British Heart Foundation

Who is the main contact?
The main contact is Dr Emma Chung, Lecturer, Department of Cardiovascular Sciences, University of Leicester. emlc1@le.ac.uk

Contact information

Type(s)
Public

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Protocol serial number
UKCRN ID: 11702

Study information

Scientific Title
Brain Injury following Cardiac Interventions (BICI)

Acronym
BICI

Study objectives
This observational study investigates brain injury following cardiac surgery involving cardiopulmonary bypass using transcranial Doppler (TCD) ultrasound, MRI, and cognitive testing.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Hospitals of Leicester NHS Trust and Derbyshire Research Ethics Committee, 18/05/2011, ref: 10/H0401/78

Study design
Observational cross-sectional study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Cardiac surgery will Cardiopulmonary Bypass

Interventions
All eligible participants are invited to take part in the study after their cardiac surgery consultation and provided with a patient information leaflet. Participants interested in taking part in the research study are scheduled in for an MRI scan and a battery of cognitive tests prior to their surgical procedure. All participants undergo intra-operative bi-lateral transcranial ultrasound monitoring of the middle cerebral artery during their cardiac surgery. This ultrasound recording of the blood flow of the cerebral arteries is recorded for the entire procedure. The participants are invited for a follow-up 6 to 8 weeks after surgery, which includes a second MRI scan and the same battery of cognitive tests. On completion, this completes the participants involvement in the study.

Intervention Type
Mixed

Primary outcome(s)
Number and size of brain lesions assessed using 3T MRI imaging (including diffusion-weighted imaging, fluid-attenuated inversion recovery, time of flight angiography, susceptible weighted imaging and T1 and T2 volumetric measurements) before surgery and 6-8 weeks post-surgery

Key secondary outcome(s))
1. Cognitive ability (including speed of information and language processing, attention and psychomotor speed) assessed using WASI test (via Block Design, Pattern Matrices, and Similarities and Vocabulary tests), Trail Making Parts A and B, WMS-III digit span task, SCOLP test and Grooved Pegboard test before surgery and 6-8 weeks post-surgery
2. Interruption to blood flow to the brain and presence of emboli during the surgical procedure assessed using intra-operative transcranial ultrasound monitoring of the middle cerebral artery
3. Presence/absence of risk factors for cognitive decline assessed by reviewing the participant's medical records

Completion date
25/05/2015

Eligibility

Key inclusion criteria
1. Undergoing cardiac surgery involving cardiopulmonary bypass
2. Native English speaker (for neuropsychological tests)
3. Eligible to undergo MRI scan

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Unable to take neuropsychological tests

Date of first enrolment
25/07/2011

Date of final enrolment
17/12/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals of Leicester NHS Trust
Glenfield Hospital
Leicester
United Kingdom
LE1 5WW

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

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

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2019		Yes	No
Results article	results	15/09/2020	06/07/2020	Yes	No
Participant information sheet	version v3	23/08/2011	28/11/2018	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes