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Effect of postconditioning on cardiac protection in children undergoing tetralogy repair

Submission date 07/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 15/11/2006	**Overall study status** Completed	
Last Edited 06/01/2021	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of postconditioning on cardiac protection in children undergoing tetralogy repair

Acronym
Postconditioning

Study objectives
Postconditioning can reduce the reperfusion injury of myocardium in open heart surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval gained on 06/05/2006 by Xiang Ya Hospital ethics committee.

Study design
Randomised, controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Infants and children with Tetralogy undergoing radical repair

Interventions
In the experimental group, the aorta is crossclamped for two cycles of 30 seconds clamping and 30 seconds unclamping onset of reperfusion after cardioplegic arrest.

In control group,the patients receive cold blood cardioplegic arrest alone without postconditioning.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

1. Postoperative Creatine Kinase - Myocardial Band (CKMB)
2. Cardiac Troponin I (cTnI)
3. Inotropic use

Secondary outcome measures
1. Mortality
2. Morbidity
3. Intensive Care Unit (ICU) stay

Overall study start date
20/09/2006

Completion date
20/04/2007

Eligibility

Key inclusion criteria
1. Patients with Tetralogy undergoing radical surgery
2. Less than 14 years old

Participant type(s)
Patient

Age group
Child

Upper age limit
14 Years

Sex
Both

Target number of participants
30

Total final enrolment
105

Key exclusion criteria
1. Tetralogy with pulmonary atresia
2. Emergency surgery
3. Palliative surgery

Date of first enrolment
20/09/2006

Date of final enrolment
20/04/2007

Locations

Countries of recruitment
China

Study participating centre
87 Xiangya Road
Changsha
China
410008

Sponsor information

Organisation
Xiang Ya Hospital (China)

Sponsor details
Central South University
No.87 Xiangya Road
Changsha
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410078

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05c1yfj14

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Trial is internally funded by the Xiang Ya Hospital (China)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2009	06/01/2021	Yes	No