

Effect of postconditioning on cardiac protection in children undergoing tetralogy repair

Submission date 07/09/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/11/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/01/2021	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Upper age limit

14 years

Sex

All

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)

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**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