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Outcomes of surgical repair of Tetralogy of Fallot in an African tertiary care centre with emphasis on post-operative pulmonary regurgitation

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2012-01-17
http://hdl.handle.net/10539/11032

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UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Dr Deliwe P Ngwezi

CLEARANCE CERTIFICATE	**M10230**
PROJECT	Outcomes of Surgical Repair of Tetralogy of Fallot in an african Tertiary Care Centre with Emphasis on Post Operative Pulmonary Insufficiency: A Retrospective Study
INVESTIGATORS	Dr Deliwe P Ngwezi.
DEPARTMENT	Paediatrics & Child Health
DATE CONSIDERED	26/02/2010
DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 26/02/2010 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Prof AM Cilliers

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...

APPENDIX B

OUTCOMES OF SURGICAL REPAIR OF TETRALOGY OF FALLOT IN AN AFRICAN TERTIARY CARE CENTRE WITH EMPHASIS ON POST OPERATIVE PULMONARY REGURGITATION

DATA COLLECTION SHEET

PATIENT DATA (Patient names will be kept confidential)

Patient Code Number: ---------- Date of birth:----------
Sex: M or F

Date of first visit:---------- Age first seen:----------

Ethnic Group: B W C I

CLINICAL DATA

CODE: YES = 1

NO = 0

ANATOMIC DESCRIPTION OF RVOT AT SURGERY

Infundibular Stenosis YES NO

PV Stenosis YES NO

If YES is it Hypoplastic PV YES NO

Supravalvar PS YES NO

Branch PS YES NO

If YES left or right or both :----------

SURGICAL MANAGEMENT

Palliation Shunt YES NO

If YES BTS CENTRAL

Age at Palliation:----------

Corrective Surgery YES or NO

If YES: Primary Repai YES or NO

Age at correction:----------

TYPE OF SURGERY	YES	NO
Muscle resection		
RVOT patch		
PV valvotomy		
TAP		
TAP+Monocusp		
Valved Homograft		
Valved Xenograft		
REDO OPERATION		
If YES: Previous TAP		
Previous valved conduit		

Indication for Redo:----------

CARDIOMEGALY ON PALPATION | Y | | N |

CARDIOMEGALY ON CXR | Y | | N |

ASSESSMENT OF PULMONARY REGURGITATION BY COLOUR DOPPLER ON ECHO POST SURGERY

ECHO NUMBER	AGE WHEN ECHO DONE (YEARS)	NO PR Grade= 1	MILD PR Grade =2	MOD PR Grade=3	SEVERE PR Grade=4
ECHO 1 (< 1 year post op)					
ECHO 2 (1-5 post op)					
ECHO 3 (>5 years op)					

ASSESSMENT OF PULMONARY REGURGITATION BY PRESSURE HALF TIME ON ECHO POST SURGERY

ECHO NUMBER	AGE WHEN ECHO DONE (YEARS)	<100m/s	>100m/s
ECHO 1			
ECHO 2			
ECHO 3			

ASSESSMENT OF PULMONARY STENOSIS ON ECHO POST SURGERY

ECHO NUMBER	AGE WHEN ECHO DONE (YEARS)	NO PS Grade=1	MILD PS Grade=2	MOD PS Grade=3	SEVERE PS Grade=4
ECHO 1 (< 1 year post op)					
ECHO 2 (1-5 years post op)					
ECHO 3 (> 5 years post op)					

ASSESSMENT OF SEVERITY OF TRICUSPID REGURGITATION ECHOCARDIOGRAPHICALLY POST SURGERY

ECHO NUMBER	AGE WHEN ECHO DONE(YEARS)	NO TR Grade =1	MILD TR Grade=2	MOD TR Grade=3	SEVERE TR Grade=4
ECHO 1 (<1 year post op)					
ECHO 2 (1-5 years post op)					
ECHO 3 (> 5 years post op)					

ASSESSMENT OF RV SIZE BY OBSERVATION ON ECHO

RV Dilated YES NO

If YES: Age of Onset Post OP: ----------

Measurement of RV size if available: RV Size 1 ---------- Age----------

RV size 2---------- Age----------

RV size 3 ---------- Age----------

ELECTROCARDIOGRAM ASSESSMENT

ECG NUMBER	AGE WHEN ECG DONE(YEAR)	VENTRICULAR ARRHYTHMIAS	1st DEGREE HEARTBLOCK	QRS AXIS	RBBB Pattern	QRS DURATION >180ms
ECG 1 (<1 year post op)						
ECG 2 (1-5 years post op)						
ECG 3 (>5 years post op)						

FUNCTIONAL CAPACITY AT TIME OF STUDY

NYHA I ☐

NYHA II ☐

NYHA III ☐

NYHA IV ☐

OUTCOME

Dead ☐

AGE OF DEATH:----------

Alive ☐

Lost to follow up Y ☐ N ☐

APPENDIX C

GRADING FUNCTIONAL CLASS CAPACITY AT TIME OF STUDY ACCORDING TO NEW YORK HEART ASSOCIATION

NYHA Class I = Patients with cardiac disease but without limitation of physical activities. Ordinary physical activity does not cause fatigue, dyspnoea or palpitations.

NYHA Class II = Patients with cardiac disease resulting in slight limitation of physical activity. Ordinary physical activity results in fatigue, dyspnoea, palpitations.

NYHA Class III = Patients with cardiac disease resulting in marked limitation of physical activity. Less than ordinary physical activity leads to symptoms

NYHA Class IV = Patients with cardiac disease resulting in inability to carry out any physical activity without discomfort.