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Early postoperative arrhythmias after pediatric cardiac surgery

Submission date 20/01/2023	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 14/02/2023	**Overall study status** Completed	
Last Edited 14/02/2023	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Early postoperative arrhythmias are a known complication of cardiac surgery; however, little data exists on pediatric patients. This prospective study was proposed to determine the incidence, and risk factors for early postoperative arrhythmias after pediatric cardiac surgery.

Who can participate?
Pediatric patients who underwent cardiac surgery at Damascus University Pediatric Hospital between July 2020 and July 2021

What does the study involve?
All patients will be evaluated for their entire stay in the intensive care unit, from postoperative admission to discharge from the pediatric intensive care unit.

What are the possible benefits and risks of participating?
By determining the risk factors for early postoperative arrhythmias, we will prevent these arrhythmias and influence the long-term survival of patients with congenital heart diseases. There are no risks of participating.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
March 2020 to November 2021

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Rahaf Ibrahim, dr.r.e345@gmail.com

Contact information

Type(s)
Principal investigator

Contact name
Dr Rahaf Ibrahim

ORCID ID
https://orcid.org/0000-0001-7216-2250

Contact details
Pediatric Department
Damascus University Pediatric Hospital
Damascus
Syria
None available
+963934518980
dr.r.e345@gmail.com

Type(s)
Scientific

Contact name
Dr Rahaf Ibrahim

Contact details
Pediatric Department
Damascus University Pediatric Hospital
Damascus
Syria
None available
+963934518980
dr.r.e345@gmail.com

Type(s)
Public

Contact name
Dr Rahaf Ibrahim

Contact details
Pediatric Department
Damascus University Pediatric Hospital
Damascus
Syria
None available
+963934518980
dr.r.e345@gmail.com

Additional identifiers

Study information

Scientific Title
Early postoperative arrhythmias after pediatric cardiac surgery: a cohort prospective study

Study objectives
This prospective study was proposed to determine the incidence, and risk factors for early postoperative arrhythmias after pediatric cardiac surgery

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/06/2020, ethics committee of Damascus University (Damascus University; +963112123664; deansoffice.medicine@gmail.com), ref: none available

Primary study design
Observational

Study design
Single-centre observational cohort study

Study type(s)
Screening

Health condition(s) or problem(s) studied
Early postoperative arrhythmias after pediatric cardiac surgery

Interventions
All patients are evaluated prospectively during their entire stay in the intensive care unit, from postoperative admission to discharge from the pediatric intensive care unit (PICU). Postoperative care will be in the PICU, with management provided by members of pediatric cardiology, pediatric critical care, and pediatric cardiac surgery staff. All the ECG records are assessed by the same pediatric cardiologist. Standard electrocardiograms (ECGs) are registered in all patients at the time of PICU admission. Continuous ECG monitoring is performed using bedside monitors during the entire PICU stay.

Intervention Type
Other

Primary outcome(s)
Arrhythmias measured using bedside monitors during the entire pediatric intensive care unit stay

Key secondary outcome(s)
Risk factors for early postoperative arrhythmias after pediatric cardiac surgery measured using the information in the patients' medical files over the entire pediatric intensive care unit stay

Completion date
15/11/2021

Eligibility

Key inclusion criteria
1. Children who had undergone cardiac surgery for corrections of congenital cardiac disease were enrolled in this study
2. Patients included were aged 14 years at most
3. Patients included had a complete medical file

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Upper age limit
14 Years

Sex
All

Total final enrolment
229

Key exclusion criteria
1. Surgery without cardiopulmonary bypass time
2. Patient age 15 years or older at the time of surgery
3. History of chronic arrhythmias

Date of first enrolment
01/07/2020

Date of final enrolment
01/07/2021

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Pediatric Department
Damascus University Pediatric Hospital

Damascus
Syria
None available

Sponsor information

Organisation
Damascus University

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
University/education

Funder Name
Damascus University

Alternative Name(s)
University of Damascus, , DU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Syria

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Rahaf Ibrahim, dr.r.e345@gmail.com. Participants' data will be available upon request. The date when data will be available is when these data are requested. Consent was obtained from the participant’s parents. These data will be anonymized. There are no ethical or legal restrictions.

IPD sharing plan summary

Available on request