

# Early postoperative arrhythmias after pediatric cardiac surgery

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<b>Registration date</b> 14/02/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 14/02/2023	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## 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**

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**Additional identifiers**

## **Clinical Trials Information System (CTIS)**

Nil known

## **ClinicalTrials.gov (NCT)**

Nil known

## **Protocol serial number**

Nil known

# **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

## **Study design**

Single-centre observational cohort study

## **Primary study design**

Observational

## **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