

Early postoperative arrhythmias after pediatric cardiac surgery

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|----------------------------------------|---------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| Submission date 20/01/2023 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 14/02/2023 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 14/02/2023 | Condition category 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

Dr Rahaf Ibrahim

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Type(s)

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

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

Secondary study design

Cohort study

Study setting(s)

Hospital, Medical and other records

Study type(s)

Screening

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

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 measure

Arrhythmias measured using bedside monitors during the entire pediatric intensive care unit stay

Secondary outcome measures

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

Overall study start date

12/03/2020

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

Age group

Child

Upper age limit

14 Years

Sex

Both

Target number of participants

200

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

Sponsor details

Faculty of Human Medicine at Damascus University

Al-Mazzeah Highway

Damascus

Syria

None available

+963112123664

deansoffice.medicine@gmail.com

Sponsor type

University/education

Website

<http://damascusuniversity.edu.sy/med/?lang=1&set=3&id=252>

ROR

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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/03/2023

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