

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### The effect of Intraoperative intravenous paracetamol administration on postoperative fever in pediatrics cardiac surgery

#### Protocol summary

##### Summary

Aims: 1-to compare fever occurrence in the first 24 hour after surgery in both groups. 2- to compare amount of rise in body temperature in the first 24 hour after surgery in both groups. Method: In this randomized, double-blind, placebo-controlled clinical, 80 children, aged 1-12 years old, presenting for open heart surgery, were entered the trial and randomly allocated in to two groups: Placebo and Paracetamol. After induction of anaesthesia, 15mg/kg intravenous Paracetamol solution was infused during 1 hour in the Paracetamol group. Patients in placebo group received 15mg/kg normal saline infusion during the same time. Since the end of operation until next 24 hours in Intensive Care Unit, axillary temperature of the two group patients was recorded in four- hour intervals. Any fever occurred during this period, had been treated with Paracetamol suppository (125 mg) and the amount of antipyretic drug consumption for each patient had been recorded. In order to examine the safety of paracetamol, patients were evaluated for drug complication at the same time. Variables: primary outcome variables were fever occurrence and mean body temperature rise in the first 24 hour after surgery. secondary outcome variables were drug side effects and amount of extra antipyretic agent used. inclusion criteria: 1-12 year old children candidate for open heart surgery exclusion criteria: previous sensitivity to paracetamol, liver disease, renal disease

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201207215506N6**

Registration date: **2012-09-24, 1391/07/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-09-24, 1391/07/03

##### Registrant information

###### Name

Mohamadhasan Abdollahi

###### Name of organization / entity

Yazd University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 35 1826 0277

###### Email address

mhabdollahi@ssu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Yazd University of Medical Sciences

##### Expected recruitment start date

2012-02-20, 1390/12/01

##### Expected recruitment end date

2012-07-04, 1391/04/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of Intraoperative intravenous paracetamol administration on postoperative fever in pediatrics cardiac surgery

##### Public title

postoperative fever

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

inclusion criteria: children, aged 1-12years old,  
presenting for open heart surgery exclusion criteria:  
were history of previous sensitivity to paracetamol, liver  
and kidney disease

#### Age

From **1 year** old to **12 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **80**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Single

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Yazd University of Medical Sciences Ethics Committee

##### Street address

Bahonar square

##### City

Yazd

##### Postal code

#### Approval date

2012-01-26, 1390/11/06

#### Ethics committee reference number

135684

## Health conditions studied

### 1

#### Description of health condition studied

fever after cardiac surgery using cardiopulmonary pump

#### ICD-10 code

T88.8

#### ICD-10 code description

Other specified complications of surgical and medical  
care, not elsewhere classified

## Primary outcomes

### 1

#### Description

Postoperative fever

#### Timepoint

In the 1st 24 hour after operation with 4 hour intervals.

#### Method of measurement

Trans-axillary

## Secondary outcomes

### 1

#### Description

Paracetamol complications

#### Timepoint

24 hour after operation

#### Method of measurement

Study questionnaire

## Intervention groups

### 1

#### Description

intervention group: After induction of anaesthesia,  
15mg/kg intravenous Paracetamol solution was infused  
during 1hour in the Paracetamol group

#### Category

Treatment - Drugs

### 2

#### Description

control group: Patients in placebo group received normal  
saline infusion with the same volume during the same  
time

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Afshar Heart Hospital

##### Full name of responsible person

##### Street address

##### City

Yazd

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Yazd University of Medical Sciences

**Full name of responsible person**  
Dr. Hasan Mozaffari

**Street address**  
Bahonar square

**City**  
Yazd

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**  
Yes

**Title of funding source**  
Yazd University of Medical Sciences

**Proportion provided by this source**  
100

**Public or private sector**  
*empty*

**Domestic or foreign origin**  
*empty*

**Category of foreign source of funding**  
*empty*

**Country of origin**

**Type of organization providing the funding**  
*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Yazd University of Medical Sciences

**Full name of responsible person**  
Dr. Mohammad Hasan Abdollahi

**Position**  
Assistant professor of anesthesiology department

**Other areas of specialty/work**

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afshar hospital

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
*empty*

**Study Protocol**  
*empty*

**Statistical Analysis Plan**  
*empty*

**Informed Consent Form**  
*empty*

**Clinical Study Report**  
*empty*

**Analytic Code**  
*empty*

**Data Dictionary**  
*empty*