

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of electroacupuncture on hemodynamic profile, postoperative pain, nausea and bleeding in pediatric tonsillectomy

Protocol summary

2020-03-13, 1398/12/23

Study aim

To evaluate the effect of electroacupuncture on pain, nausea severity and hemodynamic profile in tonsillectomy

Design

Clinical trial with control group, parallel groups, double blind, randomized with 64 patients

Settings and conduct

Patients are candidates for tonsillectomy surgery at Rasoul Akram Hospital. Participants were randomly assigned to two groups. Patients and outcome assessor are blinded to the assignments.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children candidate for tonsillectomy without adenoidectomy. Exclusion criteria: Coagulopathy or upper airway tract infection

Intervention groups

Intervention group: After induction of anesthesia and intubation, needling is performed at four points of Li4, P6, Sp1 and Sp6 by the acupuncturist. The needles remain in place for 20 minutes and stimulated with electroacupuncture. Control group: Induction of anesthesia and intubation without needling

Main outcome variables

Pain, Nausea severity, Mean arterial pressure, heart rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101026005026N12**

Registration date: **2020-03-13, 1398/12/23**

Registration timing: **prospective**

Last update: **2020-03-13, 1398/12/23**

Update count: **0**

Registration date

Registrant information

Name

Masood Mohseni

Name of organization / entity

Rasoul Akram hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6435 2326

Email address

mohseni@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of electroacupuncture on hemodynamic profile, postoperative pain, nausea and bleeding in pediatric tonsillectomy

Public title

The effect of acupuncture on pain, nausea and bleeding in tonsillectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children candidate for tonsillectomy without adenoidectomy
Exclusion criteria:
 coagulopathy upper respiratory tract infection

Age
 From **5 years** old to **12 years** old

Gender
 Both

Phase
 3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
 Target sample size: **64**

Randomization (investigator's opinion)
 Randomized

Randomization description
 The patients were randomly allocated into acupuncture and control groups using a table of random numbers.

Blinding (investigator's opinion)
 Double blinded

Blinding description
 The patients and outcome assessor (in the recovery room) are unaware of assignments.

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
 Ethics committee of Iran University of Medical Sciences

Street address
 Next to Milad Tower, Hemat Highway ,Tehran

City
 Tehran

Province
 Tehran

Postal code
 14496-14535

Approval date
 2019-12-24, 1398/10/03

Ethics committee reference number
 IR.IUMS.FMD.REC.1398.423

Health conditions studied

1

Description of health condition studied
 Pediatric tonsillectomy

ICD-10 code
 J03

ICD-10 code description
 Acute tonsillitis

Primary outcomes

1

Description
 Mean arterial pressure

Timepoint
 Before, 30-60-90-120-180 minutes after induction

Method of measurement
 Digital barometer

2

Description
 Heart rate

Timepoint
 Before, 30-60-90-120-180 minutes after induction

Method of measurement
 Digital barometer

3

Description
 Pain

Timepoint
 after being fully awake at the recovery

Method of measurement
 NRS (Numerical rating scale)

4

Description
 Nausea severity

Timepoint
 after being fully awake at the recovery

Method of measurement
 NRS (Numerical rating scale)

Secondary outcomes

empty

Intervention groups

1

Description
 Intervention group: After induction of anesthesia and intubation, needling is performed at four points of Li4, P6, Sp1 and Sp6 by the acupuncturist. The needles remain in place for 20 minutes and electrically stimulated .

Category
 Treatment - Surgery

2

Description

Control group: Induction of anesthesia and maintenance of anesthesia without needling

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram hospital

Full name of responsible person

Masood Mohseni

Street address

Hazrate Rasoole Akram Hospital, Niayesh St, Satarkhan Av, Tehran, IRAN

City

Tehran

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1449614535

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+98 21 6435 1444

Email

masood.mohseni@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyad Abbas Motavalian

Street address

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Masood Mohseni

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All individual data of the participants in this study could be shared after unidentifiable individuals

When the data will become available and for how long

6 months after publication

To whom data/document is available

Data will be available to researchers in academic positions

Under which criteria data/document could be used

Only after permission from researchers

From where data/document is obtainable

Refer to the responsible person for accessing the data
masood.mohseni@gmail.com

What processes are involved for a request to access data/document

within working days after email to the responsible person

Comments