Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

Study aim
To evaluate the effect of electroacupuncture on pain, nausea severity and hemodynamic profile in tonsilectomy

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
2020-03-13, 1398/12/23

Registrant information

Name
Masood Mohseni

Name of organization / entity
Rasul 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
Province
Tehran
Postal code
1449614535
Phone
+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
Next to Milad Tower, Hemat Highway ,Tehran
City
Tehran
Province
Tehran
Postal code
14496-14535
Phone
+98 21 6435 1444
Email
mohseni@med.mui.ac.ir
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
Street address
Hazrate Rasoole Akram Hospital,Niayesh St,Satarkhan Av
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 6435 1444
Email
masood.mohseni@gmail.com

Person responsible for scientific 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
Street address
Rasul Akram hospital, Niayesh Ave, Sattarkhan St
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 6435 2326
Fax
+98 21 6435 2328

Email
masood.mohseni@gmail.com

Person responsible for updating data

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
Street address
Rasul Akram hospital, Niayesh Ave, Sattarkhan St
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 6435 2326
Fax
+98 21 6435 2328
Email
masood.mohseni@gmail.com

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