

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Survey effect of acupressure on level of nausea and vomiting in hospitalized children undergoing tonsillectomy

Protocol summary

Study aim

Therefore the present study aims to investigate the effect of acupressure on postoperative pain relief in children aged 5 to 12 years old undergoing tonsillectomy at Amir Almomemini Therapeutic Training Center in Rasht.

Design

The present study is a randomized, blinded, sham controlled clinical trial with a parallel group design of 144 children, will be enrolled between June 2018 and September 2018.

Settings and conduct

In this study, children who have inclusion criteria will be randomly assigned into one of three intervention, control and placebo groups. The proper time for intervention will be 1 hour after tonsillectomy, then 2 to 4 hours and 6 to 8 hours after the surgery. In the intervention group, the amount of the child nausea and vomiting will be first measured and recorded, then acupressure on three acupoints will be applied. In the placebo group, pressure will be applied to the same points with the difference that the applied pressure will be very superficial. In the control group only routine care will be provided.

Participants/Inclusion and exclusion criteria

Inclusion criteria of the study included: children aged 5 to 12 years old who were under tonsillectomy and will be admitted to the surgical ward of Amir Almomemini Therapeutic Training Center in Rasht. Exclusion criteria of this study included: mental disorders, dermatological damage near acupressure zone, coagulopathy and existence of severe postoperative pain that prevented the child's ability from participating in this study

Intervention groups

This study have three intervention, control and placebo groups. In the intervention group, acupressure will be applied at three acupoints (acupuncture points) and in the placebo group, the sham acupressure will be applied. In the control group only routine care will be applied.

Main outcome variables

Nausea: vomiting.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171008036651N2**

Registration date: **2018-05-29, 1397/03/08**

Registration timing: **prospective**

Last update: **2018-05-29, 1397/03/08**

Update count: **0**

Registration date

2018-05-29, 1397/03/08

Registrant information

Name

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Name of organization / entity

Guilan University Of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-04, 1397/03/14

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey effect of acupressure on level of nausea and vomiting in hospitalized children undergoing tonsillectomy

Public title

Survey effect of acupressure on level of nausea and vomiting in hospitalized children undergoing tonsillectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

children aged 5 to 12 years old who will be under tonsillectomy in the Amir Almomenin Therapeutic Training Center in Rasht.

Exclusion criteria:

Mental disorders. Dermatological damage near acupressure zone. Coagulopathy Existence of severe postoperative nausea and vomiting that prevented the child's ability from participating in this study.

Age

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

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **144**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done as random blocks allocation. The randomization method will be selected based on the random number table so that the first child examined at the beginning of the work will be assigned in the acupressure group, the second in the control group, the third in the placebo group, the fourth in the acupressure group, and so on. Children and their parents will not be aware unaware of how to allocate to each of the three groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, children, parents, nurses and other health personnel who are in contact with the child will be unaware of the allocation of each of the three groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethica committee of Guilan University of Medical Sciences

Street address

Guilan University Of Medical Sciences, Iran Radiator Building, Imam Khomeini Blv, Rasht

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Province

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Postal code

3984141469

Approval date

2018-05-11, 1397/02/21

Ethics committee reference number

IR.GUMS.REC.1397.054

Health conditions studied

1

Description of health condition studied

Post tonsillectomy nausea and vomiting.

ICD-10 code

K91.9

ICD-10 code description

Post procedural disorder of digestive system, unspecified

Primary outcomes

1

Description

Nausea and vomiting.

Timepoint

The proper time for intervention is one hour after the operation of the tonsillectomy and then 2 to 4 hours and 6 to 8 hours after the operation.

Method of measurement

The level of nausea and vomiting will be measured using the Baxter Animated Retching Faces (BARF) scale.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, the nausea and vomiting level of the child will be first measured and recorded, and on the two sides of the Hego, Neiting and Zuslanli points on both symmetrical limbs, acupressure will be applied. The way to apply pressure is to massage deep and roughly, with the finger of the thirty-sixth

marker and to the researcher's point of view and in a clockwise direction, from 3 to 4 kilograms. Each time the pressure period will be two minutes.

Category

Treatment - Other

2**Description**

Control group: In the control group without any intervention, the children will be spoken about their feelings around the surgery (the fear of the surgery, the way of behavior of surgery room nurses) and post-surgery experience (existence of pain, lethargy and restlessness) and they also were asked questions about the number of children in family and school.

Category

Treatment - Other

3**Description**

Control group: In the placebo group, pressure will be applied on the Hego, Neiting and Zuslanli points, with the exception that the applied pressure will be very superficial.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amiralmomenin Medical and Education Center

Full name of responsible person

Somaye Pouy

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

Doctor Shadman Nemati

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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

Guilan 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**

Guilan University of Medical Sciences

Full name of responsible person

Somaye Pouy

Position

Bachelor's Degree in Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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

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Full name of responsible person

Somaye Pouy

Position

Master student of nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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